

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters  
Products Liability Litigation

) MD-15-02641-PHX-DGC

) Phoenix, Arizona

) May 4, 2018

Doris Jones, an individual,

Plaintiff,

v.

) CV-16-00782-PHX-DGC

C.R. Bard, Inc., a New Jersey  
corporation; and Bard Peripheral  
Vascular, Inc., an Arizona  
corporation,

Defendants.

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

FINAL PRETRIAL CONFERENCE

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**P R O C E E D I N G S**

THE COURTROOM DEPUTY: MDL 2015-2641, Bard IVC  
Filters Product Liability litigation, on for final pretrial  
conference in the Jones trial.

Will the parties please announce.

MR. O'CONNOR: Yes. Morning, Your Honor.  
Mark O'Connor, Ramon Lopez, co-lead. Paul Stoller,  
Shannon Clark, Lincoln Combs. And we have two of our  
paralegals with us today, Gay Mennuti, and Felice Wortman.

THE COURT: All right. Good morning.

MR. LOPEZ: Morning, Your Honor.

MR. NORTH: Good morning, Your Honor. On behalf of  
the defendants, Richard North. And joining me today are  
James Condo, Elizabeth Helm, James Rogers, Brandee Kowalzyk,  
Amanda Shelton, and -- I'm sorry, Amanda Sheridan, and  
Matthew Lerner.

THE COURT: Okay. Good morning.

I'm going to just dive right into the issues we need  
to cover, Counsel. I'm hoping we can get this done by noon.  
We'll see how we do.

I want to start first on the juror excusals for  
hardship.

I issued Docket 10844 that excused a number of jurors  
for hardship. After that order was prepared, there were four

1 additional juror questionnaires that came in that I hadn't  
2 reviewed that were on the disk that you received. And those  
3 were Jurors 15, 76, 117, and 141. So those should have been  
4 on your disks.

10:02:09 5 MR. O'CONNOR: I didn't hear the last two,  
6 Your Honor.

7 THE COURT: 15, 76, 117, and 141.

8 I have since reviewed those, and I'm going to excuse  
9 Juror 141 for hardship. That individual indicates that they  
10 have a single income for a family, they live paycheck by  
11 paycheck, and it would be a financial hardship. So I'm going  
12 to add 141 to the list that was in the order that I entered.

13 Juror 15 also requested to be excused for hardship,  
14 but simply said a loss of wages would be a hardship with no  
15 explanation. So I think we need to have Juror 15 come in so  
16 that we can hear more about exactly what hardship that would  
17 create.

18 In addition to that, two of the jurors that were on  
19 the disk that you received that I did not excuse for hardship  
20 have subsequently sent in letters saying a hardship has  
21 developed. One of those is Juror Number 6. Juror Number 6's  
22 letter indicates that they have a close family member who was  
23 recently diagnosed with ALS, Lou Gehrig's disease, which, as  
24 you know, is a fatal condition, and that their family is  
10:03:26 25 gathering in Colorado during the month of May to provide

10:03:29 1 support. So I'm going to excuse Juror 6 for hardship.

2 Also, Juror Number 177 sent in a letter indicating  
3 that his wife had accepted a new position in Colorado, and  
4 they were moving immediately. In fact, they moved to Colorado  
10:03:43 5 on April 29th. So I'm going to excuse Juror 177.

6 And then, finally, we received another questionnaire  
7 that came in in the last couple of days, I think it might have  
8 been handed to you this morning, that is Juror 41. I'm going  
9 to excuse Juror 41 because of the hardship that would be  
10:04:01 10 caused to that juror's employer.

11 So in addition to the numbers that were listed in the  
12 order that I entered, I'm excusing 141, 6, 177, and 41.

13 So the question, for plaintiff's counsel first, is  
14 whether you object to any of the hardship excusals that I have  
10:04:27 15 made?

16 MR. O'CONNOR: No objections.

17 THE COURT: How about from the defendants?

18 MR. NORTH: No objections, Your Honor.

19 THE COURT: All right. So we then will excuse  
10:04:34 20 everybody listed at Docket 10844, plus Jurors 141, 6, 177, and  
21 41. And they will not be asked to come in for jury selection.

22 Do plaintiffs have any challenges for cause based on  
23 the questionnaires?

24 MR. O'CONNOR: Yes, Your Honor.

10:05:01 25 Would you like me to proceed through my list?

10:05:04 1 THE COURT: Yeah. Let's do them one at a time.

2 MR. O'CONNOR: All right. Number 8. And, again,  
3 that was a response to question number 63, indicating the  
4 juror could not be fair and impartial.

10:05:27 5 THE COURT: I see no explanation. Do you have any  
6 understanding of the reason for that?

7 MR. O'CONNOR: I don't think he gave an explanation,  
8 although he did say that most lawsuits are frivolous. He  
9 also --

10:05:42 10 THE COURT: Where? Where?

11 MR. O'CONNOR: I thought I read that in number 63,  
12 Your Honor.

13 THE COURT: There is nothing in number 63.

14 MR. O'CONNOR: For Juror 8?

10:05:53 15 THE COURT: Juror 8.

16 It's a woman, by the way.

17 MR. O'CONNOR: Hold on one second. I might have  
18 wrote the number down. Excuse me, it's number 3. I  
19 apologize. I wrote it down wrong. I couldn't read my own  
10:06:09 20 handwriting. It's Number 3 I'm moving on, Your Honor.

21 And it is Number 3 who indicated --

22 THE COURT: I see. I see what it says on question  
23 63. That's the basis?

24 MR. O'CONNOR: For cause, inability to be fair and  
10:06:35 25 impartial.

10:06:35 1 THE COURT: All right. Response from the defense?

2 MR. NORTH: Your Honor, I believe the statement is  
3 equivocal. The juror says -- the prospective juror says that  
4 he or she "tends to think" and says "most lawsuits," not all  
10:06:48 5 lawsuits. I think this would benefit from further questioning  
6 to see whether -- how strong that feeling is.

7 THE COURT: I'm going to grant the challenge for  
8 cause to Juror 3. He indicates clearly that he does have a  
9 reason to think he could not be fair and impartial. He does  
10:07:59 10 express the view that most lawsuits like this are frivolous.

11 So I will grant the challenge for cause to Juror 3.

12 Mr. O'Connor, your next.

13 MR. O'CONNOR: Yes, Your Honor. Number 25. Based on  
14 response to question 63, concerned about waste of taxpayer  
10:08:21 15 money on personal injury cases, especially when lawyers are  
16 suing -- doing so much instigation and advertising, and he  
17 said that that's is a reason he could not be fair and  
18 impartial.

19 THE COURT: Defense response?

10:08:43 20 MR. NORTH: Your Honor, again, I believe that  
21 statement is somewhat equivocal. The juror is saying that he  
22 or she is concerned about the waste of taxpayer money, but in  
23 no way suggests that they could not assess the case based upon  
24 the evidence presented at trial.

10:09:06 25 THE COURT: I'm going to grant the challenge for

10:09:08 1 cause. This juror also says, in question 43, people just want  
2 money. In question 59, there's a reference to frivolous  
3 lawsuits. In question 63, there's a reference to lawyers  
4 instigating and advertising. I think the juror's clearly  
10:09:36 5 indicated they can't be fair and impartial.

6 So I will grant the challenge to Juror 25.

7 The next, Mr. O'Connor?

8 MR. O'CONNOR: That was 25.

9 Yes, Your Honor. Number 66.

10:10:10 10 And, again, Your Honor, if I remember correctly, this  
11 juror actually -- I think he also works in the medical field.  
12 He wrote a paper on IVC filters, and he suggested yes to the  
13 question 63 and explained that he may not be able to -- well,  
14 he said: "Due to my medical experience and the report I did  
10:10:35 15 on IVC filters in college, I might be impartial."

16 THE COURT: Defense response?

17 MR. NORTH: Your Honor, again, we would suggest that  
18 this is equivocal in response to number 63. First of all,  
19 it's not quite clear what he's saying. He's saying "I might  
10:11:11 20 be impartial." I think he might saying "I might not be  
21 impartial," but that's equivocal.

22 He does not say specifically what his medical  
23 experience brings to the table as far as affecting his bias,  
24 if any, or his paper on the IVC filter. And I would suggest  
10:11:30 25 that would need follow-up voir dire questioning.

10:11:33 1 THE COURT: I am not going to grant the challenge for  
2 cause to this juror. It looks to me as though the answer to  
3 63 is saying that because he has had some experience with IVC  
4 filters, he may not be viewed as impartial, but he doesn't  
10:11:49 5 indicate why he could not be fair and impartial. So I'm going  
6 to deny the challenge for cause. We can inquire further  
7 during voir dire.

8 MR. O'CONNOR: All right, Your Honor. The next is  
9 Juror 67 based upon his response to question 63.

10:12:26 10 And I would also draw the Court's attention to his  
11 response to question 44, where he discusses feelings about the  
12 FDA.

13 THE COURT: Defense response?

14 MR. NORTH: Your Honor, I think his response to  
10:13:01 15 number 63 is somewhat equivocal and a little bit difficult to  
16 follow. He says "I may encounter discussions to this or any  
17 other lawsuit related to other medical device manufacturers."

18 Sounds to me like he's concerned he might be exposed  
19 to some sort of extraneous information.

10:13:20 20 And, in addition, I don't believe his response  
21 regarding the FDA indicates any clear bias or anything, just  
22 some familiarity, mostly with the process.

23 So we would submit that further voir dire questioning  
24 would be necessary with this juror.

10:13:35 25 THE COURT: I'm going -- I am not going to grant the

10:13:38 1 challenge for cause on this juror at this time. I think we  
2 need to ask further questions. It's not clear to me that this  
3 juror believes he would be unfair or partial. It looks like  
4 he is more concerned that he has some knowledge in the  
10:13:55 5 industry and works for a similar company and that can have an  
6 effect, but I think we need to ask questions on that. So I  
7 will deny the challenge for cause to Juror 67.

8 MR. O'CONNOR: Thank you.

9 91. Again, Your Honor, based upon his response to  
10:14:11 10 63, Juror 91 said that he cannot be fair and impartial. He  
11 believes the justice system has become corrupted and  
12 politicized during the last Obama administration, and then he  
13 gives us an additional response.

14 He's already asking questions and speculating about  
10:14:49 15 other issues that he believes may be important to his  
16 decisions.

17 I think this juror clearly has indicated in his  
18 response that he's going to start with feelings against the  
19 plaintiff's case and won't start on a level playing field. So  
10:15:02 20 for that reason, we'd move to strike 91.

21 THE COURT: Defense response, Mr. North?

22 MR. NORTH: Your Honor, I believe that his  
23 explanatory statement on page 13 in further response to  
24 question number 63 indicates a willingness on his part to  
10:15:22 25 explore the evidence and to listen to the evidence. And he's

10:15:26 1 recognizing that the introduction in the juror questionnaire  
2 did not explain the details, which he would -- of the  
3 incident, which he would need to hear more about.

4 I would also draw the Court's attention to question  
10:15:38 5 number 55, where he states conversely that he thinks he might  
6 have trouble being impartial if he believed that the  
7 manufacturer of the product had harmed himself or a family  
8 member or someone close.

9 So I submit to you that -- or would suggest that this  
10:15:56 10 juror requires or would need further questioning just to see  
11 if they can keep an open mind, because these answers seem to  
12 indicate a willingness to listen to the evidence.

13 THE COURT: I'm going to grant the challenge for  
14 cause to this juror. The juror indicates that he does not  
10:16:16 15 think he could be fair and impartial. The reason he gives in  
16 63 is he thinks the justice system has become corrupted and  
17 politicized. He states in other locations that he believes  
18 many cases are without merit.

19 And he states in his explanation on page 13, "The  
10:16:33 20 plaintiff was also negligent." He seems to have come to that  
21 conclusion, which appears to be related to what he said on  
22 page 8, that it's up to the patient to thoroughly research  
23 available designs.

24 So I'm going to grant the challenge for cause to  
10:16:49 25 Juror 91.

10:16:55 1 MR. O'CONNOR: Your Honor, in response to 63 and  
2 several questions, Juror 105 did not provide any responses.

3 THE COURT: Therefore --

4 MR. O'CONNOR: Pardon me?

10:17:17 5 THE COURT: Therefore what?

6 MR. O'CONNOR: Well, I suppose that he's inviting us  
7 to ask him further questions, so I'll move on to the next one.

8 THE COURT: All right. I agree.

9 MR. O'CONNOR: Thank you.

10:17:32 10 The next one on my list is 116, Your Honor. He  
11 already is saying that -- he answered yes, he cannot be fair  
12 and impartial, and he's already -- and in further explanation,  
13 he talks about being "a business professional who has seen  
14 first-hand such lawsuits contribute to nothing to society but  
10:18:10 15 pad the pockets of greedy personal injury lawyers. I know" --  
16 I can't read the other thing. I guess he's saying he knows  
17 some good and honest ones, but he's rare.

18 I think based upon that response it's clear that the  
19 plaintiff would start in an uneven playing field with that  
10:18:37 20 juror.

21 THE COURT: All right. Mr. North?

22 MR. NORTH: Your Honor, in response to question  
23 number 43, this juror states that he would try to be as  
24 impartial as possible.

10:18:46 25 In response to question 49, he states that people

10:18:48 1 that have truly been a victim deserve justice.

2 And he also, as Mr. O'Connor just mentioned, on  
3 page 13, notes that despite his view of some attorneys, that  
4 there are good and honest plaintiffs' attorneys.

10:19:02 5 We would submit that these responses show a  
6 willingness to keep an open mind that would at least warrant  
7 further questioning during voir dire.

8 THE COURT: All right. I'm going to grant the  
9 challenge for cause to Juror 116. He says on page 8,  
10:19:16 10 question 144, that he has a strong pro business bias.

11 On page 9, he says that in a very small percentage of  
12 cases he could rule for a plaintiff, but the evidence better  
13 be ironclad.

14 He says on 63, question 63, it would be hard not to  
10:19:38 15 be biased.

16 And on page 13, he says, Lawsuits contribute nothing  
17 but to pad the pockets of greedy personal injury lawyers.

18 I'm going grant the challenge for cause to Juror 116.

19 MR. O'CONNOR: That, I believe, is the entirety of  
10:20:02 20 our challenges today, Your Honor.

21 THE COURT: Okay.

22 MR. O'CONNOR: With the understanding -- again, it's  
23 going to be the same as the last trial, we're going to be able  
24 to follow up with each of these jurors?

10:20:07 25 THE COURT: Right.

10:20:08 1 All right. Defense?

2 MR. NORTH: Your Honor, I did want to raise one as  
3 far as hardship goes that was not on the Court's list. That  
4 is Number 94. The Court may have made a decision to wait and  
10:20:21 5 explore that further, but he mentions his hardship in an  
6 unusual place, on page 12 of the questionnaire, and just in  
7 the event that the Court might not have seen that since it was  
8 not up front, I wanted to draw it to the Court's attention.

9 THE COURT: I did not see that. Let me read it.

10:20:51 10 I'm going to grant the hardship challenge to that  
11 juror. He indicates that he lives paycheck to paycheck. Even  
12 with a daily jury stipend, he would not be able to pay his  
13 bills if he were called.

14 So we will add 94 to the hardship list.

10:21:13 15 Let me just make a note of that in the right place.

16 Okay. Challenges for cause, Mr. North?

17 MR. NORTH: Yes, Your Honor. Beginning with Juror  
18 Number 48. This is an unusual case.

19 This juror, in response to question number 40,  
10:21:37 20 acknowledges -- I'm not sure if it's a he or she, but  
21 acknowledges -- it's a she -- acknowledges that she is aware  
22 of the \$3.6 million -- she doesn't mention the word "Booker,"  
23 but that verdict that occurred in this court at the end of  
24 March.

10:21:57 25 She says later in 63 that she can be fair. But I am

10:22:01 1 very concerned, and we are, the defendants, about having a  
2 juror who has specifically seen press on a verdict in the same  
3 litigation that occurred in this courtroom only five weeks  
4 ago.

10:22:14 5 I'm also concerned that if we question her on voir  
6 dire in front of the other jury panel members, none of whom  
7 have mentioned this verdict, except for her, we run a serious  
8 risk of tainting the entire pool. And we therefore would  
9 argue she should be challenged for cause.

10:22:36 10 THE COURT: Plaintiff's response.

11 MR. O'CONNOR: Well, Your Honor, I mean, she's very  
12 unequivocal that she can be fair and impartial. And, as a  
13 matter of fact, in 57 and 58, she tells us she thinks the  
14 number of lawsuits are too high and that she thinks money  
10:22:48 15 damages are too high.

16 I think any issues that there may be a concern about  
17 her so-called tainting the pool, we can address at the  
18 sidebar. But I think this juror should be allowed -- we  
19 should be allowed to further question her to find out -- and  
10:23:04 20 it is a her -- about her feelings.

21 But when you take all her responses as a whole, it  
22 appears to me that she is fairly rounded in her feelings about  
23 issues relating to litigation. But, most importantly, 63,  
24 she's clear, she's unequivocal she can be fair and impartial.

10:23:21 25 THE COURT: I'm not going to grant the challenge for

10:23:23 1 cause at this point. But what we ought to do during voir dire  
2 is this, and I'll trust you to remember this, but neither of  
3 you, whoever is doing the follow-up questions, should ask her  
4 a question in front of the jury panel. What we should do is  
10:23:42 5 after we're through of all of the questioning the full panel,  
6 we'll excuse them and ask Juror 48 to remain behind so we can  
7 ask questions on this issue without the risk of her giving an  
8 answer in front of the entire jury pool.

9 So I'll make a note of that. You all make a note  
10:24:02 10 that as well. And that way --

11 And, Traci, could you remind us?

12 THE COURTROOM DEPUTY: Yes, sir.

13 THE COURT: And that means you shouldn't ask any  
14 follow-up questions of Juror 48 on any issue. We should wait  
10:24:13 15 and deal with her after we've excused the panel, because we  
16 don't want to create the risk that in response to some other  
17 question she mentions that verdict.

18 Let me make a note here.

19 I don't want, by suggesting -- by describing this  
10:24:54 20 procedure to suggest that if some other juror mentions the  
21 verdict that we have to abandon the whole panel and start  
22 over. We'll talk then about what to do. But let's deal with  
23 Juror 48 in that way to minimize that risk.

24 All right. Your next one, Mr. North?

10:25:10 25 MR. NORTH: Your Honor, Juror Number 100.

10:25:23 1 Juror Number 100 says in response to question  
2 number 36, rates a medical device manufacturer as a 1.

3 In response to question 43, the juror states that he  
4 believes that medical device manufacturers do not take  
10:25:40 5 responsibility when devices fail.

6 He continues on page 13 to say that lives, quote,  
7 have been ruined, close quote, that manufacturers should pay  
8 dearly.

9 And in response to question number 63, he says he  
10:25:55 10 can't be a fair juror because he is against medical device  
11 manufacturers.

12 THE COURT: Mr. O'Connor?

13 MR. O'CONNOR: We don't object.

14 THE COURT: I'm going to grant the challenge for  
10:26:05 15 cause to Juror 100.

16 MR. NORTH: Your Honor, the next one is Number 123.

17 123 has very sort of odd or different responses.  
18 This gentleman says in response to question number 38 that FDA  
19 people are corruptible, that cleared products do not  
10:26:42 20 necessarily work, and cleared products are potentially deadly.

21 More concerning, in question number 12, he makes the  
22 point of advising us that he believes in jury nullification.  
23 And while he says in response --

24 THE COURT: You said question 12. I think you mean  
10:26:59 25 question 64.

10:27:03 1 MR. NORTH: Oh, I'm sorry.

2 MR. O'CONNOR: 64?

3 MR. NORTH: Yes.

4 THE COURT: Yes. He says, "I believe in jury  
10:27:07 5 nullification."

6 MR. NORTH: I'm sorry, you're right. On page 12.  
7 That's how I misread that.

8 He says he believes in jury nullification, while in  
9 the preceding question he says he knew of no reason to be --  
10:27:19 10 he could be fair and unbiased -- reason why he could not be  
11 fair and unbiased. I believe that the belief in jury  
12 nullification is extremely disturbing because it indicates an  
13 unwillingness to follow the Court's instructions and the law.

14 THE COURT: Mr. O'Connor.

10:27:38 15 MR. O'CONNOR: Well, this isn't a case about -- I  
16 mean, there's going to be FDA issues, but everything else, he  
17 pretty much stays neutral, Your Honor, about his feelings  
18 about lawsuits. I think we should at least be able to follow  
19 up with him to find out what he means about jury nullification  
10:27:59 20 when he said unequivocally he could be fair and impartial.

21 THE COURT: I'm going to grant the challenge for  
22 cause to Juror 123. He is unequivocal in saying he believes  
23 in jury nullification. That tells me he would not follow the  
24 Court's instructions, so I will grant the challenge for cause.

10:28:21 25 MR. NORTH: The next one, Your Honor, is 132.

10:28:25 1 Juror 132 describes frequently a personal event that  
2 seems to affect his views of things. In response to question  
3 number 35, he says his father sued a manufacturer, and I  
4 believe it was Boston Scientific, because of a faulty -- he  
10:28:44 5 calls it "defib," I assume he means a defibrillator, which  
6 almost killed his father.

7 In response to question number 43, he says that the  
8 defibrillator shortened his father's life.

9 He also talks about the same incident in response to  
10:28:59 10 question numbers 52, 54, and 55. In 55, the response to 55,  
11 he calls the product defective.

12 In response to question number 63, he says he can be  
13 fair, without much explanation, or any explanation, but I'm  
14 very concerned about this frequent mention of a situation with  
10:29:20 15 his father where he believes that the defective medical device  
16 shortened his father's life.

17 THE COURT: Mr. O'Connor?

18 MR. O'CONNOR: Well, the device is not a filter.  
19 Everywhere else he has indicated that he's fairly rounded and  
10:29:36 20 can be neutral. I noted when he talks about PI lawyers, he  
21 puts us at a 3, but he puts medical device companies at a 6.

22 So all of that -- I mean, he's had an experience with  
23 one device. He didn't indicate it was an IVC filter, and  
24 certainly has not indicated any inability not to be fair and  
10:29:51 25 impartial in this case.

10:29:52 1 THE COURT: I am not going to grant the challenge to  
2 Juror Number 132. I think that that requires further  
3 questioning. He did indicate he could be fair and impartial.  
4 There's clearly areas that need to be inquired into, but we'll  
10:30:07 5 let that happen during voir dire.

6 MR. NORTH: The next one, Your Honor, is 150.

7 Juror Number 150. Beginning in response to question  
8 number 44, this gentleman states that he has general sympathy  
9 for plaintiff and that he -- plaintiffs, and he assumes that  
10:30:31 10 defendants have insurance.

11 In response to question number 49, he assumes that a  
12 plaintiff has gone through, quote, quite an ordeal, close  
13 quotes, if going to court.

14 In response to questions 57 and 58, he says that the  
10:30:50 15 number of lawsuits are too few and damage awards too low.

16 Page -- I mean question 59, he believes that damages  
17 caps are set by insurance companies.

18 Again, in response to question number 62, he  
19 advocates or says he's a supporter of jury nullification.

10:31:09 20 And then in response to question number 63, he  
21 indicates that he does not believe he can be fair.

22 THE COURT: Mr. O'Connor?

23 MR. O'CONNOR: I didn't hear the -- the last one he  
24 said he couldn't be fair?

10:31:22 25 MR. NORTH: 63.

10:31:23 1 THE COURT: 63.

2 MR. O'CONNOR: We're not going to oppose that motion.

3 THE COURT: I'll grant the challenge for cause to

4 Juror 150.

10:31:34 5 MR. NORTH: The last one, Your Honor, is 168.

6 And I must say this looks like a law school

7 hypothetical for challenges for cause.

8 In response to questions number 37 and 38, he

9 indicates he has strong views -- or she indicates she has

10:31:57 10 strong views about the FDA.

11 In response to question number 36, she rates

12 corporations and medical device manufacturers as a 1.

13 In question number 33 -- I'm sorry, 43, her response

14 is, and this is a direct quote, "big companies are killing

10:32:15 15 people."

16 In response to question number 4, she says "big

17 companies are keeping medication from people."

18 In question --

19 THE COURT: You said question 4. I think you meant

10:32:26 20 44.

21 MR. NORTH: 44, I'm sorry.

22 In response to question number 54, she says that

23 she's had a personal bad experience with a medical device.

24 And then in response to question number 63, she

10:32:41 25 indicates she cannot be fair because "big business is" --

10:32:48 1 "could be killing" -- it is hard to really decipher what she's  
2 saying, but clearly it is not a favorable view of  
3 corporations.

4 THE COURT: Mr. O'Connor?

10:33:01 5 MR. O'CONNOR: I think she's pretty neutral in her  
6 strong views because she doesn't like PI lawyers either.

7 I just think we should be able to ask her questions  
8 about what she -- she hasn't specifically said that she has  
9 some bias against IVCs, and we're going to see people that  
10:33:18 10 have experience, I think, with a lot of different medical  
11 devices, so I think this is a juror that we should at least be  
12 allowed to question.

13 THE COURT: Okay. I'm going to grant the challenge  
14 for cause to Juror 168. She says she can't be biased and she  
10:33:29 15 gives ample reasons in support.

16 So that means we are granting challenge for cause to  
17 Jurors 3, 25, 91, 100, 116, 123, 150, and 168.

18 Does that look right, Traci?

19 THE COURTROOM DEPUTY: Yes.

10:33:55 20 THE COURT: Everybody in agreement on that?

21 So we will not have -- I saw nods.

22 MR. O'CONNOR: Yes, Your Honor.

23 MR. LOPEZ: Yes, Your Honor.

24 THE COURT: We will not have those eight jurors come  
10:34:07 25 in either, in addition to the folks that we have excused for

10:34:12 1 hardship.

2 All right. Let's talk about the number of people we  
3 should have come in.

4 We had 60 come in for the Booker trial. We -- when  
10:35:11 5 we got to the follow-up questions, I asked you at sidebar only  
6 to ask follow-up questions of the first 40 to save time. And  
7 at the end of that process we excused for hardship or cause a  
8 total of 21 of the 60. So we had 29. We hadn't questioned  
9 the other 20, but we had a large number left.

10:35:39 10 And that made me think that we perhaps can do this  
11 with 50 jurors, rather than 60. We have to have 15 at the end  
12 of the process for you each to exercise your three peremptory  
13 strikes and have nine left over. That means we've got 35  
14 jurors we can go through. We don't want to end up with too  
10:36:00 15 few, so I always err on the side of having more come in rather  
16 than less. But given our experience in Booker, it seemed to  
17 me there's a pretty safe chance of getting our 15 if we bring  
18 in 50, but I want to get your thoughts on that before I make a  
19 decision.

10:36:19 20 MR. O'CONNOR: Well, Your Honor, I understand your  
21 point, but the difference between 50 and 60, I think 60 would  
22 lean more towards not falling into that trap of cutting it too  
23 close, so that's why I think we would prefer to have 60 come  
24 in here.

10:36:39 25 MR. NORTH: Your Honor, I tend to agree. I do think

10:36:42 1 we're probably safe with 50, but I think there are two wild  
2 cards. Number one is you never can predict how many people  
3 just don't show up; and, number two, we do have one juror, as  
4 we know, prospective juror who has heard about the last  
10:36:55 5 verdict, and I do fear we might get some more responses that  
6 come out through voir dire.

7 THE COURT: Okay, we'll have 60 come in.

8 We need again for this trial to have you compile a  
9 witness list that can be handed out in the jury room so the  
10 jurors can review it before they come up, just like we did  
11 last time.

12 I'd like you to get that list to us --

13 Well, Traci, is it soon enough if they get it to us a  
14 week from today, the 11th?

10:37:31 15 THE COURTROOM DEPUTY: Yes.

16 THE COURT: So get us that list by the 11th in the  
17 same form we used before. We'll make copies and have it  
18 distributed to the jurors in the jury assembly room on the  
19 15th, when they gather.

10:37:44 20 Let's talk for a minute about the voir dire  
21 questions.

22 Plaintiff's counsel, you proposed two additional  
23 questions on punitive damages. Do you want to make any  
24 comments on why you think those are appropriate?

10:38:05 25 MR. O'CONNOR: Well, yes, Your Honor. Just that

10:38:09 1 in -- I think we should know if there are jurors out there  
2 that they may well have views one way on damage awards, but a  
3 different view on punitive damages awards. And I think our  
4 questions were fairly neutral and posed the same way you could  
10:38:31 5 ask them, and we could see that issue quickly and question  
6 that issue very quickly with jurors to find out what their  
7 feelings are, because there may well be people out there that  
8 just have feelings that are all for it and others that may be  
9 all against the concept of punitive damages. And so since  
10:38:52 10 it's going to be an issue, we think we should be able to  
11 question the prospective panel on that.

12 All right. Defense views?

13 MR. NORTH: Your Honor, we would object to these two  
14 questions for a number of reasons. First of all, we think  
10:39:05 15 this topic is generally covered in the questionnaire, which  
16 asks for opinions as to whether damage awards are too high or  
17 too low, and also talk in terms of -- address caps on damages.

18 We would also note that the Court -- or the  
19 plaintiffs proposed adding something about this to the juror  
10:39:23 20 questionnaire for Jones, and my recollection is the Court  
21 denied that revision, noting that you thought it would be too  
22 confusing.

23 But most important, at this late date we are only  
24 presenting follow-up questions, or asking follow-up questions  
10:39:38 25 of these jurors. There are no other general voir dire

10:39:42 1 questions being asked except the very general things that the  
2 Court asks.

3 I think to have these two essentially substantive  
4 questions as the only substantive questions about issues in  
10:39:53 5 the case is simply going to unduly emphasize that issue and  
6 will be prejudicial.

7 THE COURT: All right.

8 Mr. O'Connor?

9 MR. O'CONNOR: The only other point I would make,  
10 Your Honor, because there's going to be a question on the  
11 verdict form, there may be a question on the verdict form, I  
12 think it's important that we at least find out how people feel  
13 about that going into this trial.

14 THE COURT: Okay.

10:40:52 15 I am not going to ask these questions. And the  
16 reason I am not is a concern that most members of the jury  
17 panel won't know the difference between punitive damages and  
18 regular damages. So to get the answer that we're really  
19 after, whether they oppose punitive damages, I think I'd need  
10:41:14 20 to explain what punitive damages are, as we do in the  
21 instructions. And I think an explanation like that at the  
22 beginning of the case would place an undue emphasis on  
23 punitive damages.

24 I didn't include it in the questionnaire, even though  
10:41:28 25 it was considered. The arguments today haven't persuaded me

10:41:31 1 that that is incorrect. And I think there's ample information  
2 in the questionnaire to elicit the jurors' views on the  
3 lawsuits, on caps on damages, on plaintiffs lawyers, and  
4 corporations. I think the jurors' views are pretty clearly  
10:41:48 5 explored in the questionnaire. So I am not going to ask those  
6 voir dire questions, and I will ask the same voir dire  
7 questions that I asked at the Booker trial. So the only ones  
8 that will be other than the sort of can-you-serve questions  
9 will be -- and whether they know anybody who is on either side  
10:42:08 10 of the courtroom representing clients, will be the FDA  
11 questions that I asked the first time around.

12 All right. Let's talk --

13 MR. O'CONNOR: Your Honor, may I follow up one point  
14 you just made?

10:42:20 15 THE COURT: Yes.

16 MR. O'CONNOR: Like we encountered in the last trial,  
17 and we encounter this often, when we get to questions,  
18 follow-up questions and responses, I feel they are too high,  
19 are we going to be permitted to question further on what do  
10:42:37 20 they mean by "too high," and if that goes over to the punitive  
21 damage issue, are we going to be permitted to follow up on  
22 that?

23 THE COURT: You can -- if they have an answer in  
24 their questionnaire that they think verdicts are too high, you  
10:42:57 25 absolutely can follow up on that and ask what they mean. If

10:43:00 1 the topic of punitive damages comes up in a way that you think  
2 you need to ask about punitive damages, ask to talk at sidebar  
3 and we'll talk at that point.

4 MR. O'CONNOR: Fair enough.

10:43:12 5 THE COURT: All right.

6 I think that covers everything on jury selection.

7 Any questions or issues you all want to raise on the  
8 general subject of jury selection?

9 Okay.

10:43:32 10 Trial time. As you've seen in a couple of orders,  
11 particularly Docket 10587, I've given plaintiff 28 hours,  
12 defendants 27 hours. As I indicated in a sort of  
13 interlineated paragraph on deposition designations, I intend  
14 to hold us to those time limits this time around in the case.  
10:43:54 15 So please be very conscious of that in the early stages of the  
16 case.

17 With this time allocation, if each side reserves one  
18 hour for the punitive damages phase of the case, then we'll  
19 get the case to the jury by the morning of Thursday, May 31st,  
10:44:12 20 which will leave time for deliberation that day, and will  
21 leave all of Friday in the event we need to go into punitive  
22 damages or deliberations go over into Friday.

23 I'm facing the same situation in this trial that I  
24 was in the last, which is I am not available the following  
10:44:30 25 Monday or anytime during that week. So we've got to finish

10:44:33 1 this trial by the end of Friday, June 1st. But I think we'll  
2 be able to do that if we get the case to the jury on Thursday  
3 morning or even at the end of the day Wednesday. We'll have  
4 two days for deliberation and punitive damages. So I think  
10:44:47 5 we'll be okay on that.

6 The jury instructions that you submitted, the  
7 preliminary instructions you gave me was one long text. It  
8 wasn't broken out by numbers. I couldn't tell what you'd  
9 changed from before. We went through and tried to match them  
10:45:07 10 to the numbers in the first one. It looked like to me you  
11 just copied what was in a transcript. So I'm just going to  
12 give the same preliminary instructions I did before.

13 Any objection to that?

14 MR. O'CONNOR: No.

10:45:19 15 MS. HELM: None, Your Honor. Actually, that was the  
16 Word, we just resubmitted the Word document that you used to  
17 give the preliminary instructions.

18 THE COURT: That wasn't the Word document. You  
19 resubmitted the transcript. The Word document was numbered by  
10:45:31 20 specific jury instructions, and that's not what we got from  
21 you.

22 MR. CLARK: Your Honor, let me apologize to the Court  
23 for that. We intended to submit the Word document, but we  
24 couldn't find it, so what we did a redline of the actual  
10:45:44 25 instructions that were given from the transcript for the

10:45:47 1 convenience of our purposes in comparing that there really  
2 were no changes other than names and filter names. And at  
3 some point in that process we accepted the changes, and that  
4 is what got submitted as opposed to the instructions, so it  
10:46:00 5 was just a snafu in the moment of filing seven or eight things  
6 that day. So I apologize to the Court.

7 I did have a couple of concerns about what the Court  
8 has proposed. If I could just --

9 THE COURT: About the preliminary instructions?

10:46:11 10 MR. CLARK: Yes.

11 THE COURT: Okay.

12 MR. CLARK: They're fairly minor, I think,  
13 Your Honor.

14 With respect to the Court's instruction 1.5, and I  
10:46:21 15 apologize that we did not flag this earlier, but the last  
16 paragraph where it kind of is the defendants' response to the  
17 plaintiff's allegations, the second sentence, Your Honor, kind  
18 of adds some more meat on the bone as opposed to just  
19 responding to the two sentences that the paragraph above has  
10:46:40 20 concerning the nature of the claims. It gives some additional  
21 kind of flesh to the defendants' defenses here, which I think  
22 is probably not necessary or appropriate in this context at  
23 the beginning of the trial.

24 So we would ask that second sentence of the last  
10:46:55 25 paragraph be stricken. It really just would turn it into

1 something that responds tit for tat to the plaintiff's  
2 allegation.

3 THE COURT: Defendants' response?

4 MR. NORTH: Your Honor, I think that's a fair and  
5 very concise rebuttal. In the paragraph beforehand, it says  
6 specifically what the plaintiff's allegations are, that she  
7 alleges that the filter was defectively designed and that  
8 defendants failed to warn about its risks. And then in the  
9 paragraph below, it rebuts that simply by saying we deny those  
10 allegations, and in place of that contend that risks  
11 associated with the filters are understood and are considered.

12 THE COURT: I can see both sides' views on this.

13 I don't view it as a critical issue. But what I'm  
14 going to do is shorten that second sentence of the last  
15 paragraph simply to say "Defendants contend that risks  
16 associated with Bard IVC filters are understood by the medical  
17 community," period. So I'm going to take out the second half  
18 of that sentence. That gets the point across, but doesn't  
19 further elaborate on their positions.

20 All right. Further comment on preliminary  
21 instructions?

22 MR. CLARK: Yes, Your Honor. With respect to  
23 instruction 1.8, that was given in Booker. And when I  
24 compared that instruction, which indicates the jury should  
25 treat the two defendants separately, to the proposed -- to the

10:49:55 1 proposed agreed upon instruction number 2 for finals, which  
2 says that you should treat the two defendants jointly, I feel  
3 those are inconsistent messages we're sending to the jury.

4 THE COURT: All right. I'm going to replace that  
10:50:07 5 with instruction number 2 that I gave in the final  
6 instructions. I think that's a good catch.

7 Other comments?

8 MR. CLARK: The only other ones, Your Honor, you had  
9 a question mark after 2.2, Stipulations of Fact. And --

10:50:26 10 THE COURT: Yeah. The reason I do that is I don't  
11 give those at the beginning. I don't know if I'll give them.  
12 I typically will give them if they become relevant. In this  
13 case, when you give your first stipulation, I'll use it. When  
14 you present the first deposition, I'll use the deposition  
10:50:42 15 understanding. So they're just there to stop me from reading  
16 when I'm giving the instructions.

17 MR. CLARK: And the only other housekeeping type one  
18 would be instruction 2.4, which is deposition in lieu of live  
19 testimony. I think that the last paragraph there that gives  
10:50:56 20 the standard instruction not to place any significance on the  
21 behavior --

22 THE COURT: Right.

23 MR. CLARK: Since it's all going to be video depos, I  
24 don't know that we need that.

10:51:06 25 THE COURT: Right. Yeah. I won't read that. I

10:51:07 1 didn't read it last time. But, yeah, that's correct.

2 Any comments from the defendants on the preliminary  
3 instructions?

4 MR. NORTH: None, Your Honor.

10:51:13 5 THE COURT: Okay. On your final instructions, I'm  
6 going to have you do those over again.

7 I got four different documents. The first one is  
8 what you agree on, but about halfway through you stop  
9 numbering the instructions. So I can't, without looking at  
10:51:30 10 each instruction, compare that to the original.

11 The second is the plaintiff's suggestions, but it's  
12 not redlined against the original, so I can't tell what's  
13 changed without going word for word.

14 The third is the defendants' suggestions. That is  
10:51:43 15 not redlined, so I can't tell what's been changed without  
16 going word for word.

17 The fourth is a combination. Those aren't redlined  
18 against the originals and not redlined against each other.

19 So to use these, I've got to take the original  
10:51:57 20 instruction, the plaintiff's version, and the defendants'  
21 version, and I've literally got to go through word by word to  
22 see what's being changed from the original and what you  
23 disagree on.

24 So I'm not going to do that. What I'm going to do is  
10:52:14 25 have you do this, and I'm going to ask you to get this to me

10:52:18 1 by Tuesday of next week. Give me the original set of  
2 instructions from Booker, the final set, with the same  
3 instruction numbers at the top. And if you don't change  
4 anything and you're in agreement, just give it to me in that  
10:52:33 5 form.

6 But if you're changing something in the instruction,  
7 then cross out what the -- like, for example, let's say the  
8 third paragraph the plaintiff has a proposal, put in the  
9 plaintiff's third paragraph that crosses out my language that  
10:52:47 10 shouldn't be given and adds in bold and italics what the  
11 plaintiff is adding. And if the defendant has a different  
12 proposal, put in underscored what the defendant is proposing.  
13 That way, I can look at them, I can see, okay, here's my  
14 original language, here is what the plaintiff proposes, here  
10:53:03 15 is what the defendant proposes, and then put those arguments  
16 in at the end as to who is right.

17 And if you want to add an instruction that's not in  
18 the original and it relates to that one, just put it as the  
19 next page. It won't have a number on it because it wasn't one  
10:53:20 20 of the original instructions. It can be plaintiff's proposed  
21 instruction, and you can put it there.

22 That way, I can go through and see exactly what is  
23 being changed from the original, where you disagree, and what  
24 you want to add that wasn't added before. And that will be  
10:53:32 25 much easier than the four documents that were submitted.

10:53:36 1 MS. HELM: May I ask one quick question?

2 THE COURT: Yeah.

3 MS. HELM: If the only change is the plaintiff's name

4 and G2 to Eclipse --

10:53:44 5 THE COURT: You don't need to do anything. Just put

6 that in, because I know that's a change we're making.

7 MS. HELM: Okay. I just wanted to make sure you

8 didn't want that, because we would have to redline everything.

9 But I think the ones we agree on, that's the only change.

10:53:56 10 THE COURT: Right. I'm going to read them all again,

11 so I'll see that. You don't have to underline that.

12 MS. HELM: Okay.

13 THE COURT: Any questions on that?

14 MR. CLARK: None from the plaintiff, Your Honor.

10:54:07 15 THE COURT: Okay.

16 All right. Let's talk about the final pretrial order

17 and go through that. There's several matters I want to raise

18 from that.

19 All right. You have stipulations on pages 3 and 4.

10:54:51 20 In the last trial I read those stipulations just before

21 opening statements. You want me to do that again?

22 MR. O'CONNOR: We would be agreeable to that,

23 Your Honor.

24 MR. NORTH: Yes, Your Honor, that's fine.

10:55:17 25 THE COURT: Okay.

10:55:19 1 Let me make a note.

2 So I will read the stipulations on pages 3 and 4 just  
3 before opening statements.

4 Jeff, could you print those two pages for me so I  
10:55:47 5 could just put them in the book, since I haven't printed the  
6 whole pretrial order.

7 All right.

8 There is, in your discussion of contested issues of  
9 fact and law, beginning on page 5, no mention of the defense  
10:56:12 10 of failure to mitigate damages. But there is a jury  
11 instruction proposed on failure to mitigate damages.

12 So the question I have is whether the defendants are  
13 going to be asserting that defense in this case?

14 MS. HELM: Your Honor, frankly, it depends on the  
10:56:30 15 testimony, but most likely yes. And we would ask that the  
16 pretrial order be amended before you enter it so that we can  
17 put that as a contested issue.

18 THE COURT: Any comments from plaintiff?

19 MR. CLARK: Yeah, Your Honor. We think that would be  
10:56:44 20 inappropriate. Comparative fault and contributory negligence  
21 are not issues in this case. We have that confirmed from the  
22 defendants. So, at best, that would be hugely confusing to  
23 the jury to have evidence about how Mrs. Jones should have  
24 done things different to, quote, mitigate her damages when  
10:57:02 25 she's not being blamed in this case. And particularly in

10:57:05 1 light of your ruling on the fact that anemia evidence would be  
2 the only evidence as far as unrelated causes or medical  
3 conditions that would be at issue in the case on a causation  
4 basis, it would be -- there's not any evidence at all that  
10:57:21 5 following doctors orders or treating her anemia would somehow  
6 lessen her damages.

7 I think the Court's order is an issue as to  
8 causation, but it's either anemia that relates to certain  
9 complaints or the filter. But it is not a situation where it  
10:57:36 10 could be a little bit of both.

11 So that would be the only context in light of where  
12 we are with the facts here where mitigation of damages could  
13 come into play, and that is just going to be very confusing  
14 because there is just no evidence whatsoever that doing  
10:57:47 15 anything differently would have an impact on the damages that  
16 are at issue in this case.

17 THE COURT: You seem to make two arguments there.  
18 The first one seemed to be that because they are withdrawing  
19 any contributory negligence defense, they cannot assert a  
10:58:00 20 failure to mitigate defense because it would be confusing.

21 MR. CLARK: That's argument number one.

22 THE COURT: Have you seen any law that says those  
23 defenses are linked and if you get rid of one you have to  
24 abandon the other?

10:58:16 25 MR. CLARK: Well, I just think from the standpoint of

10:58:17 1 what -- if they're blaming her for not doing something, which  
2 is the context in which this arises, that is fault-based  
3 argument. This is not the type of case where you have, you  
4 know, a car crash case where someone is rear-ended and clearly  
10:58:29 5 not at fault but instead of going to a chiropractor ten times  
6 she goes 50 times. This instruction does not fit on the facts  
7 of this particular case.

8 THE COURT: But that's your second argument, which is  
9 that the facts don't support a failure to mitigate defense.

10:58:43 10 MR. CLARK: Yes.

11 THE COURT: Right?

12 MR. CLARK: They're a little mixed up together, but  
13 that is exactly the problem. We don't want the jury to have  
14 the same confusion.

10:58:52 15 THE COURT: Okay.

16 MR. CLARK: They can't ding her twice for the same  
17 thing. You know, it's either they can say that this condition  
18 is not related because it relates to other medical conditions  
19 that preexisted this, but they can't essentially backdoor a  
10:59:01 20 fault-based argument through a mitigation of damages  
21 instruction.

22 THE COURT: Well, they clearly have the right to  
23 assert a failure to mitigate defense as a matter of law if  
24 they choose to elect that defense. So the fact that they've  
10:59:12 25 withdrawn a contributory negligence or comparative fault

10:59:16 1 defense doesn't eliminate it, in my view. I understand the  
2 argument that there are no facts in the case that could  
3 constitute a failure to mitigate.

4 And I'm interested in defense counsel's thought on  
10:59:25 5 that.

6 MS. HELM: Your Honor, one example of the facts that  
7 relate to failure to mitigate is the plaintiff has testified  
8 that she is worried about the remaining strut, and that she  
9 testified in her deposition that she was going to see a doctor  
10:59:44 10 to determine whether it was a mental thing or do I really have  
11 anything to worry about.

12 But we have information -- we have a stipulation that  
13 she has not been to the doctor since 2016. So I believe that  
14 fact alone shows a failure to mitigate one of the claims that  
11:00:01 15 they're making in the case. Or at least an argument that  
16 there's a failure to mitigate.

17 MR. NORTH: What about anemia?

18 MS. HELM: And then, of course, Your Honor, there is  
19 the question of the other injuries -- the other physical  
11:00:15 20 conditions. And I'm aware of your order on that. But --

21 THE COURT: I heard Mr. North say "what about  
22 anemia." That, to me, is not a failure to mitigate argument,  
23 because if she's tired because she isn't treating her anemia,  
24 that is not a failure to mitigate the fatigue she would  
11:00:36 25 experience from the strut; it's a failure to address the

11:00:38 1 fatigue she's experiencing from the anemia. So it's a  
2 causation issue. Is the tiredness caused by the anemia or the  
3 strut? It's not a failure to mitigate issue.

4 I understand your point about failure to mitigate.

11:00:53 5 You understand, I assume, from my order my view that if you  
6 start going down the road of saying she didn't get medical  
7 care, I'm going to let plaintiff put in evidence that she  
8 didn't because she couldn't afford it. So those, to me, sort  
9 of will go hand in hand.

11:01:08 10 MS. HELM: Your Honor, I'm aware of that. And we  
11 have direction from the Georgia appellate court on that issue  
12 as well. So, yes, we are aware of it. But the facts based on  
13 her testimony are that failure to mitigate is an appropriate  
14 defense and an appropriate charge.

11:01:23 15 THE COURT: Okay. Well, the issue I need to decide  
16 right now is whether I should preclude defendants from  
17 potentially raising a failure to mitigate defense, and I can't  
18 decide now that I should.

19 It may be correct that I shouldn't instruct the jury  
11:01:37 20 if there is no evidence to support it, but I can't decide that  
21 now.

22 So I'm going to deem on this record, so we don't have  
23 to file another version, the failure to mitigate defense as  
24 having been added to the final pretrial order as an issue in  
11:01:52 25 the case. And when we settle jury instructions, we'll talk

11:01:55 1 about whether or not that is appropriate. And if there's  
2 objections along the way on evidence, I'll certainly be happy  
3 to hear that.

4 On pages 13 and 14, you all have raised a question of  
11:03:07 5 whether the Georgia statute, Section 51-12-5.1(e), precludes  
6 an award of punitive damages in this case. And there are  
7 brief arguments made on those pages.

8 I have a question for defense counsel first.

9 The statute states, quote, in a tort case in which  
11:03:45 10 the cause of action arises from product liability, there shall  
11 be no limitation regarding the amount which may be awarded as  
12 punitive damages, period.

13 Only one award of punitive damages may be recovered  
14 in a court in this state from a defendant for any act or  
11:04:07 15 omission if the cause of action arises from product liability,  
16 regardless of the number of causes of action which may arise  
17 from such act or omission.

18 So it's clear that what I think the statute is saying  
19 is a defendant can be punished only once for an act or  
11:04:31 20 omission.

21 In this case, it seems to me there's some obvious  
22 things. One is the defendant was not punished in the Booker  
23 trial for the act or omission of defective design or strict  
24 product liability failure to warn because there was a defense  
11:04:52 25 verdict on all three of those claims. Defective design, both

11:04:56 1 strict liability and negligence, and then strict product  
2 liability failure to warn.

3 So those acts or omissions were not -- and that's  
4 what gave rise to a punitive damages claim.

11:05:15 5 It also seems clear to me, having not looked at any  
6 case law, that the defendants' alleged failure to warn with  
7 respect to the G2 filter in Booker is not the same act or  
8 omission as the defendants' alleged failure to warn with  
9 respect to the Eclipse filter in Jones. It's a different  
11:05:37 10 failure to warn at a different point in time.

11 So just on the basis of that thinking, it seemed to  
12 me that this statute wouldn't preclude an award of punitive  
13 damages in this case. I'm interested in defense counsels'  
14 thoughts on that issue, and then we need to figure out if this  
11:05:58 15 is something we need to brief.

16 MR. NORTH: Your Honor, first of all, I would just  
17 note that there is a dearth of authority in Georgia as to what  
18 the impact of this statute is and many of the sort of  
19 interesting issues and interpretation issues the Court just  
11:06:10 20 mentioned.

21 That being said, the Court may have a point as far as  
22 design goes. I'm not sure that you can parse out the strict  
23 liability failure to warn from the negligent failure to warn  
24 and say there were different acts or omissions leading to one  
11:06:28 25 verdict versus the other. I mean, that's part of our

1 posttrial motions in that particular case. So I'm not sure  
2 you can make that argument.

3 As far as whether the failure to warn with regard to  
4 the Eclipse would be different from the failure to warn with  
11:06:46 5 regard to the G2, I would submit that we're going to have to  
6 see how the evidence develops.

7 A lot of the plaintiff's pretrial filings suggest  
8 things such as that the Eclipse is essentially the very same  
9 filter as the G2, that there are core design problems, there  
11:07:04 10 are core warning problems with the two filters. I think a lot  
11 will depend upon how the evidence comes in. We certainly are  
12 not asking this Court to make any decision at this point, but  
13 we did want to flag it and we are going to try to preserve our  
14 record on that issue as the case proceeds.

11:07:22 15 THE COURT: Okay. It sounds like you're not asking  
16 for a ruling now, then.

17 MR. NORTH: No, not at all, Your Honor.

18 THE COURT: So I'll reserve this issue.

19 Does plaintiff's counsel want to say anything on it?

11:07:32 20 MR. STOLLER: Your Honor, I guess we want to make the  
21 point to reiterate what you said, which is on its face it does  
22 not appear to apply to the claims where there was no liability  
23 found. And as to the failure to warn in the Booker case where  
24 there was liability, there are distinct acts at issue in this  
11:07:49 25 case with respect to the failures to warn.

11:07:52 1 I also would suggest, Your Honor, as sort of a  
2 practical matter, the defense has filed motions to overturn  
3 the verdict in Booker. If that verdict is overturned and the  
4 statute even applied, for a various number of reasons that  
11:08:08 5 we've raised, and it doesn't apply, there would be no prior  
6 punitive damage.

7 And so it seems to me regardless of any of these  
8 issues, this issue should go to the jury. There should be a  
9 decision on it. If the jury awards punitive damages and we  
11:08:25 10 later engage in argument and you decide for whatever reason  
11 that the statute applies, it should be applied after the fact.  
12 I think this needs to go to the jury under any circumstances.

13 THE COURT: Okay. I'm going to just leave this issue  
14 in the final pretrial order. I'm not going to do anything  
11:08:43 15 with it. If defendants wish to raise it at some later point  
16 in the trial, I'll leave it up to you to do that.

17 On page 15 of the final pretrial order, we have the  
18 section on disputed issues of law. And the next three pages,  
19 doesn't seem to me -- don't seem to me to include any disputed  
11:08:59 20 issues of law. I mean, it's just statements of law. And  
21 there's no dispute identified, although there is some point  
22 where defendants say we don't agree with all the cites, but I  
23 don't see any issues in those.

24 It seems to me that the first place an issue is  
11:09:17 25 raised actually isn't until we get to page 20, and there's a

11:09:25 1 question whether the defendants can offer evidence at trial  
2 that the FDA never instituted an enforcement action.

3 Am I correct that there is no issue between page 15  
4 and page 20 that I need to resolve?

11:09:39 5 MR. STOLLER: I believe that's correct, Your Honor.  
6 I think the jury instructions resolve any issues of dispute on  
7 these other legal issues, and we'll abide for that. For  
8 whatever reason, they didn't like our citations and so  
9 they're -- I think those legal principles, though, are by and  
11:09:52 10 large undisputed.

11 MS. HELM: We agree there's nothing for you to  
12 resolve.

13 THE COURT: Okay. There is the issue raised on  
14 page 20 and 21 that I -- it actually goes over to 22, that I  
11:10:01 15 did resolve in Booker about whether defendants can put in  
16 evidence a lack of FDA enforcement action. I didn't know if  
17 plaintiffs were just preserving the record on that or if you  
18 wanted me to revisit that issue. That was not something that  
19 was raised at the hearing we had on revisiting issues, that I  
11:10:21 20 recall.

21 MR. LOPEZ: Well, we'd like to revisit it,  
22 Your Honor. I mean, I went back and I looked at the history  
23 of how this whole issue about FDA evidence developed, and I  
24 refer the Court to his order on March 1, 2018.

11:10:47 25 THE COURT: What's the docket number?

11:10:51 1 MR. LOPEZ: Docket number 10258. Very last page.

2 THE COURT: That's where I said I'd resolve it at  
3 trial.

4 MR. LOPEZ: Pardon me?

11:11:02 5 THE COURT: Is that where I said I'd resolve at  
6 trial?

7 MR. LOPEZ: No. It actually says this: Defendants  
8 may, however, present evidence and argument explaining the  
9 reasons why Bard filters were not recalled, the FDA's  
11:11:14 10 potential involvement in any recall effort, and the fact that  
11 warnings about failure rates and increased risk could not be  
12 based on MDR and MAUDE data alone.

13 As the Court knows, the objection we had was just the  
14 blanket, did the FDA take any action to recall this device.  
11:11:39 15 Of course we made our 403 objections at the time. And I think  
16 when you see the way that was argued and you see the way that  
17 evidence comes in, I don't know that there's any greater 403  
18 violation than the insinuation that for some reason -- that  
19 somehow the FDA involved themselves in an investigation of  
11:12:01 20 that issue.

21 THE COURT: Let me interrupt you for a minute,  
22 Mr. Lopez, just to make sure I've got the context right.

23 MR. LOPEZ: Okay.

24 THE COURT: What was the number you just cited?

11:12:08 25 MR. LOPEZ: The docket number, Your Honor?

1 THE COURT: Yeah.

2 MR. LOPEZ: Yes. 10258.

3 THE COURT: Okay. There is a later order on this  
4 issue. It is 10323. And it's reflecting what I did at the  
5 final pretrial conference in the Booker case on March 2nd, and  
6 it says: For reasons stated in more detail on the record, the  
7 Court will not exclude evidence and argument by defendants  
8 that the FDA took no enforcement action with respect to the G2  
9 filter or evidence regarding the information defendants  
10 provided to the FDA in connection with the 510(k) process.  
11 The Court concludes that evidence regarding a lack of FDA  
12 action is relevant to the negligent design and punitive  
13 damages claim.

14 And then I cite the *Browning* case that's been cited  
15 again. And I went back yesterday and looked at the transcript  
16 of the final pretrial conference and there was a more detailed  
17 discussion of it there.

18 So I think -- we then at trial had a discussion about  
19 whether or not the lack of FDA action was a proper hearsay --  
20 could be subject to a proper hearsay objection. We had a  
21 sidebar. I looked at some case law over a break and concluded  
22 that the silence of the FDA was not hearsay and therefore  
23 there wasn't a hearsay objection.

24 I only say that to make sure I'm understanding where  
25 we got to in Booker in the context of what you're saying. If

11:13:40 1 you think I've got that wrong, I want to hear why.

2 MR. LOPEZ: No, I think --

3 THE COURT: In light of that, would you -- I was  
4 thinking about that while you were talking, so start over with  
11:13:48 5 the point you're making now.

6 MR. LOPEZ: So in looking at the pretrial order and  
7 the defendants' position on why they think that should come  
8 in, if you look at -- this is again the pretrial order,  
9 page 21.

11:14:02 10 THE COURT: This is the Jones pretrial order?

11 MR. LOPEZ: Yes, Your Honor.

12 THE COURT: Okay.

13 MR. LOPEZ: "The fact that the defendant had never  
14 been subjected to regulatory action with respect to the  
11:14:10 15 claimed defect tends to negate allegation that the  
16 configuration was a dangerous design." I mean --

17 THE COURT: That's a quote from the *Browning* case.

18 MR. LOPEZ: Right. But then if you go on to the next  
19 page -- I mean, I'm sorry, to the bottom of that, "that the  
11:14:27 20 FDA did not institute enforcement action necessitating such a  
21 result is relevant to the reasonableness of Bard's actions in  
22 continuing to market the Eclipse filter at the time plaintiff  
23 received her filter."

24 THE COURT: So where are you reading now?

11:14:43 25 MR. LOPEZ: This is at the bottom of page 21.

11:14:48 1 And I think what we have here, Your Honor, we have a  
2 situation -- and I'll read -- I think maybe I should read --  
3 my next comment should be in the context of the case they  
4 cite, and the case they cite is the *Cantor Fitzgerald &*  
11:14:58 5 *Company, Broyles versus Cantor Fitzgerald*, and where the court  
6 would allow the scope and --

7 THE COURT: I'm sorry. Excuse the interruption,  
8 Mr. Lopez. I can't see where they're citing that case.

9 MR. LOPEZ: On page 22.

11:15:15 10 THE COURT: Oh. Over on page 22.  
11 On their third argument?

12 MR. LOPEZ: Right.

13 THE COURT: Okay.

14 MR. LOPEZ: Now, this is allowing the scope and  
11:15:24 15 outcome of an investigation with respect to action by a  
16 government entity, and they claim that this is relevant to  
17 rebut any allegation or insinuation by plaintiff that Bard  
18 violated any FDA regulation.

19 Now, the problem we have in this case, Your Honor, is  
11:15:45 20 that -- now, look it, if there was evidence that the FDA  
21 performed an investigation or that there was an FDA  
22 department, I mean, we don't even know -- there's going to be  
23 no evidence as to whether or not the people at FDA who were  
24 involved in any aspect of the Eclipse filter or any other  
11:16:06 25 filter have as part of their responsibility to even discuss

11:16:10 1 recall or even to initiate recall or have an authority to  
2 recall a product.

3 So what this does, it leaves the impression with the  
4 jury, a very false impression, that FDA is somehow following  
11:16:24 5 this device, investigating it, paying close attention to how  
6 this drug -- how this device is performing, and somehow has  
7 gone through a deliberative process.

8 So what we're doing is we're telling the F- -- we're  
9 telling this jury that the FDA has a state of mind that it's  
11:16:44 10 okay to continue to sell this device, because that is the only  
11 impression that they want to leave with the jury when they say  
12 the FDA has not taken any action with respect to recall or any  
13 action in telling them not to design the case -- that's not  
14 the FDA's duty. And I just think it's false and misleading  
11:17:01 15 and, as you said in your order with respect to cephalad  
16 migration, this may prompt a jury decision based on a motion.

17 In other words, the mere fact that they're able to  
18 say that the FDA did not take action, they did not say to  
19 redesign it, they did not say to recall it, the only  
11:17:28 20 impression that the defense is trying to leave with the jury  
21 is that the FDA went through some deliberative process or they  
22 investigated this, and they made a decision internally and  
23 that the state of mind at FDA was it was okay to continue to  
24 sell this device because it was safe and effective.

11:17:43 25 And I just think that's -- I mean, that's as 403 as

11:17:49 1 it comes, Your Honor, in this case. In other words, who at  
2 FDA even considered whether or not there should be a recall or  
3 redesign?

4 We have no ability, as you know, Your Honor, to  
11:18:02 5 discover that part of the case. We can't ask anyone at FDA,  
6 why didn't you institute any recall against this device? Why  
7 didn't you tell them to redesign the device? The jury's never  
8 going to hear about that. Alls they're going to hear is that  
9 the FDA didn't do any of those two things, leaving the  
11:18:22 10 impression they must think that everything is okay with  
11 respect to the design and the fact this device can continue to  
12 be sold.

13 THE COURT: Okay. I understand that point.

14 Did you have other points you wanted to make,  
11:18:32 15 Mr. Lopez?

16 MR. LOPEZ: Yeah. There was -- there is a -- you  
17 know, I -- just so the Court knows, there are FDA regulations  
18 and guidance documents that deal with recall. And this is a  
19 Recalls, Corrections and Removals of Devices, and this is a  
11:18:56 20 U.S. Food and Drug Administration guidance document, where it  
21 states that "a recall is a voluntary action that takes place  
22 because manufacturers and distributors carry out their  
23 responsibility to protect the public health and well-being  
24 from products that present a risk of injury or gross deception  
11:19:18 25 or are otherwise defective."

11:19:20 1 This is a statement by FDA. The same document says,  
2 "It is the rare occasion that FDA ever initiates a recall  
3 process."

4 In other words, this is part of the case that I think  
11:19:31 5 that we have to be able to put in front of the jury before  
6 they can just say FDA didn't initiate a recall of this device.  
7 There has to be some evidence as to whether or not that issue  
8 was even before FDA. Did the FDA even consider a recall? Or  
9 whether or not -- in fact, they even say in their papers that  
11:19:54 10 this is FDA protecting the public, the regulator who is  
11 supposed to protect the public is saying, we don't need to  
12 recall it and you don't need to redesign it. And that is just  
13 as misleading and prejudicial as it gets, Your Honor, without  
14 any underlying evidence or information as to what was really  
11:20:16 15 going on at FDA or whether or not the FDA is even considering  
16 this.

17 There are other issues. If they initiate a recall,  
18 there are regulations that come into play where they have to  
19 do all sorts of things. They have to -- notice issues, they  
11:20:32 20 have to go out and actually tell doctors, make sure that the  
21 patients are aware of these things. And they know if they  
22 have to do that, if they do that. That's when FDA gets in  
23 recalls, is after a company voluntarily decides to recall a  
24 product or stop selling it. That's when the recall evidence  
11:20:54 25 and the recall laws and the federal regulations regarding

11:20:58 1 recalls come into play.

2 And, again, there is no way that they can dispute  
3 that most recalls, the overwhelming majority of recalls are  
4 voluntary, and FDA rarely, if ever, gets involved in recalling  
11:21:09 5 medical devices.

6 But the jury is going to think that they do.

7 THE COURT: Okay. I understand that point.

8 Defense response?

9 MR. NORTH: Your Honor, we submit respectfully that  
11:21:17 10 nothing has changed since the Court's previous ruling that the  
11 Court just cited from, I believe it was Document 10323. It is  
12 absolutely clear under *Browning versus Paccar* that this  
13 evidence of the lack of regulatory enforcement is relevant  
14 under Georgia law to the issue of a defect.

11:21:38 15 I would note that Mr. Lopez is correct, there are  
16 voluntary recalls in that point. There are voluntary recalls  
17 that are not initiated by the FDA. But nine times out of ten,  
18 it is a dialogue between the agency and the company as to  
19 whether one should occur. Most companies will do a recall  
11:21:57 20 when the FDA suggests it or talks about it before they go to  
21 formal action.

22 The question that I believe was posed to the  
23 witnesses, consistent with what the Court had ruled,  
24 consistent with *Browning versus Paccar*, was whether the FDA  
11:22:10 25 had ever suggested to Bard, to the knowledge of the witness

11:22:17 1     testifying, that the filter be recalled. And we submit that,  
2     on the face of *Browning versus Paccar*, is highly relevant  
3     evidence and should be admissible.

4             THE COURT: Okay. I'm going to go back and reread  
11:22:31 5     *Browning* in light of this discussion, and I'll include my  
6     ruling on that in the order that comes out after today.

7             All right. There is a discussion on page 23  
8     regarding Dr. Kandarpa. I ruled at the Booker final pretrial  
9     conference that because he had not been disclosed under  
11:22:55 10    Rule 26(a) or identified in interrogatory answers, he could  
11    not be used at trial.

12            I'm not seeing any facts that have changed, but I'm  
13    interested in plaintiff's view on why there should be a  
14    different ruling now.

11:23:13 15           MR. LOPEZ: Well, it was brought to my attention that  
16    these responses that were given in the case specifics were,  
17    even if he had been named at the time, there wouldn't have  
18    been time, I guess, under the rules to have taken his  
19    deposition. I don't want to -- that is a fact that even if  
11:23:27 20    his name -- even if he had been disclosed in response to those  
21    interrogatories, it would have been too late for his  
22    deposition to be taken.

23            THE COURT: Well, but isn't it also true, Mr. Lopez,  
24    that you never identified him in your Rule 26(a) disclosures,  
11:23:42 25    which would have come earlier?

11:23:43 1 MR. LOPEZ: Well --

2 MR. STOLLER: Your Honor, there were no 26(a)  
3 disclosures in these cases.

4 THE COURT: Okay.

11:23:50 5 MR. LOPEZ: These are response to interrogatories,  
6 right at the end of our case specific discovery.

7 THE COURT: When we had the discussion at the final  
8 pretrial conference, I read yesterday about the absence of  
9 26(a) disclosure, we were just all mistaken? We had a  
11:24:04 10 discussion about that at the last final pretrial conference.

11 MR. STOLLER: At the last -- I'm sorry, Your Honor.

12 THE COURT: At the final pretrial conference, we  
13 talked about Kandarpa and the fact that it wasn't included in  
14 the 26(a) disclosures.

11:24:17 15 MR. STOLLER: Are you saying in the Booker case?

16 THE COURT: Yeah.

17 MR. LOPEZ: I thought we did. I'll have to check the  
18 record. But I actually thought we did say -- because I  
19 remember someone doing what Mr. Stoller just did, whispered in  
11:24:30 20 my ear --

21 THE COURT: Well, do defendants disagree that the  
22 only place this would have been disclosed was in an  
23 interrogatory answer?

24 MR. NORTH: I'm trying to recall, Your Honor. I  
11:24:44 25 don't believe there were disclosures under the rule separate

1 and apart from these interrogatories, but I would have to go  
2 back and look, to be honest. If there were, he certainly was  
3 not disclosed.

4 But as far as time frame goes, they filed their  
5 responses to these interrogatories on July 28 of 2017.

6 Discovery was still ongoing to some extent at that point.

7 There were depositions that continued into August on these  
8 particular bellwether cases.

9 They supplemented their responses to interrogatories  
10 on August 15 of 2017. They never disclosed Dr. Kandarpa until  
11 the day before -- night before the pretrial conference in  
12 Booker. If they had -- regardless of the timing, if there was  
13 one week left in fact discovery or whatever the bellwether  
14 cases, if we needed additional time at that point to go depose  
15 somebody that had just been named, we certainly could have  
16 come to the Court and asked. But we weren't even given that  
17 opportunity.

18 And I think it's a little artificial at this point to  
19 say that because those interrogatories were not responded to  
20 until soon before the close of fact discovery that, oh, it  
21 doesn't matter, that we wouldn't have been able to depose him  
22 anyway. I would strongly disagree that that is a valid  
23 argument because if he had been disclosed, as he was required  
24 to be disclosed, we could have gone and deposed him or sought  
25 the Court's permission at that point.

11:26:14 1 THE COURT: Mr. Lopez?

2 MR. LOPEZ: I was going -- let me just -- I only  
3 bring that up because I think when -- in deciding this issue,  
4 we have to look at the substantial justice that might be  
11:26:24 5 served by allowing him to testify versus the prejudice or the  
6 burden to the side that doesn't want us to have this evidence.

7 He was revealed in the -- I mean, first of all  
8 they've known about him since the EVEREST trial. They know  
9 who Dr. Kandarpa is. It is not like this is a surprise  
11:26:42 10 witness. We offered to allow him to be deposed prior to the  
11 Booker trial.

12 Since the Booker trial, there have been discussions.  
13 In fact, he's going to be deposed in the state court case.  
14 Not until June. And I would submit that if they'd like to  
11:27:00 15 expedite that, we can probably make an arrangement to have  
16 that deposition taken before this case commences. I know that  
17 only gives us a week.

18 The Court knows from looking -- I mean, there was a  
19 back and forth about these documents, about the difference  
11:27:13 20 between what Dr. Kandarpa's company that he worked for says in  
21 particular meeting minutes or medical monitoring minutes  
22 versus what was in Bard's files. Those documents are very  
23 important. This is a medical monitor who recommended that  
24 Bard reconsider the design of the G2 filter, and also said  
11:27:35 25 that they had an inordinate number of complications in the

11:27:40 1 EVEREST trial.

2 So the same lawyers that are here today are the same  
3 lawyers that are going to have this doctor's deposition taken  
4 in -- relative to a state court case.

11:27:52 5 Now, I understand -- Your Honor, I still want to make  
6 this argument because I think the justice to be served by  
7 allowing a witness like that to testify in this case on these  
8 issues certainly is outweighed by any prejudice or  
9 inconvenience to the parties. And we'll work with defense  
11:28:09 10 counsel to get this done.

11 But if the Court is not inclined to allow us to do  
12 that, at the very least, so we don't have to spend the time we  
13 spent in the Booker trial to get in obviously relevant  
14 documents, and documents that were produced to us as part of a  
11:28:26 15 business record and part of the production in this case by  
16 Bard, even though they're Bates stamped by somebody else, and  
17 documents that were clearly documents of an agent of Bard, at  
18 the very least, we would ask this Court to allow us to bring  
19 Dr. Kandarpa in to lay a foundation for those documents. That  
11:28:45 20 is not being a fact witness. That is just him being like a  
21 custodian of records, to come in and say, yes, these are my  
22 meeting minutes that I submitted to Bard when I was involved  
23 in the EVEREST trial and, yes, just to lay the foundation so  
24 we don't have to spend day after day sometimes to get in  
11:29:05 25 documents that are extremely relevant to our case and that

1 were produced to us by Bard. I don't think he's a fact  
2 witness when we just bring him in for that purpose.

3 THE COURT: Okay. I understand that point.

4 Okay. I will include my thoughts on this in the  
5 order that comes out after today.

6 Mr. North?

7 MR. NORTH: Your Honor, I'd just like to mention a  
8 couple of things.

9 They make a point about the fact we obviously knew  
10 who this doctor was. That's true. We've known his identity.  
11 But we have known many, many doctors have been involved with  
12 this filter over the course of the years. We would still be  
13 doing discovery if we tried to run out and depose every  
14 doctor. They had an obligation to disclose him if they wanted  
15 to use him, number one.

16 Number two, they've known about him since 2016. They  
17 were asking witnesses questions about him and documents he was  
18 on a year earlier. They had plenty of time to disclose him as  
19 somebody they intended to use if that's what they wanted to  
20 do.

21 I would note, too, that if this was that important to  
22 them, it seems to me, in all fairness, they should have come  
23 to the Court immediately after the Booker case and said,  
24 Your Honor, we would like to revisit this question now so that  
25 the defendants will have time to depose him before the next

11:30:38 1 trial. Instead, they're saying, oh, they can go depose him  
2 now, when we are, what, eight, ten, 12 days before the trial  
3 date. That's not fair, we would submit, and we would submit  
4 this is trial by ambush to try that.

11:30:51 5 We would lastly note that I don't think there's -- I  
6 mean, I don't think it matters whether they're bringing him  
7 in, quote, as a fact witness, unquote, or simply to  
8 authenticate documents, as he suggests. They still had an  
9 obligation to disclose him as somebody they intended to use.

11:31:08 10 The interrogatory asked them to identify people with  
11 knowledge about the claims, and I quote, that plaintiff may  
12 use to support her claims. And they never did identify  
13 Dr. Kandarpa until the night before the Booker pretrial  
14 conference.

11:31:25 15 THE COURT: All right. I will get you a ruling on  
16 that issue.

17 The next issue is page 24 of the final pretrial  
18 order. It concerns a deposition of Mehdi, M-E-D-H-I, Syed,  
19 S-Y-E-D. I'm not understanding the defendants' objection.

11:31:41 20 MS. HELM: Your Honor, we simply want the deposition  
21 submitted to you for ruling on objections. It didn't happen  
22 in Booker. We have our objections drafted. We'll get them to  
23 the plaintiff. We just want it submitted. We can do it by  
24 Monday.

11:31:53 25 THE COURT: Okay. Well, you're going to be

1 submitting additional designations on Monday, just include it  
2 with those.

3 MS. HELM: Okay. We will. Thank you.

4 THE COURT: All right.

5 On page 64, the question of a motion to seal exhibits  
6 is raised. We will deal with that in the same way we did in  
7 the Booker trial. That motion will be due 21 days after the  
8 last trial transcript is placed on the docket for the Jones  
9 case.

10 You have an issue you've raised on the bottom half of  
11 page 66 about business records. And I couldn't tell if you  
12 needed me to address that today or not.

13 Anything from plaintiff on that?

14 MR. STOLLER: I don't believe so, Your Honor.

15 THE COURT: Okay.

16 MR. STOLLER: The question is the breadth of their  
17 stipulation.

18 THE COURT: Right.

19 MR. STOLLER: They told you when we were here, I  
20 forget, a month ago, that they would agree to stipulate that  
21 the documents they produced are business records. They seem  
22 to hedge their bets a bit here.

23 THE COURT: I think they said any Bard document they  
24 produce is a business record.

25 MR. O'CONNOR: And I didn't interpret it any other

1 way -- well, I should say it sounded to us like they were  
2 hedging, and so we just --

3 THE COURT: My understanding of the position of  
4 defendants if it's a document that either of the defendants  
5 created and possessed, they'll stipulate it's a business  
6 record. If it's a document somebody else created and  
7 possessed but they happened to produce in litigation because  
8 they came into its possession as part of litigation, they're  
9 not going to stipulate that it's a business record.

10 Is that correct, Mr. North?

11 MR. NORTH: I think that's it, Your Honor, exactly.  
12 There are a few like documents that came up last time that  
13 were in our production, were handwritten notes that no one  
14 knows where they came from, we're not going to stipulate as to  
15 those being business records, but yes.

16 MR. STOLLER: My point is I'm not sure that this  
17 recitation of our position is accurate. I didn't understand  
18 them to believe they were stipulating to that, and that was  
19 the concern. I didn't think -- we just --

20 THE COURT: You understand the scope of the  
21 stipulation?

22 MR. STOLLER: Yes.

23 THE COURT: Okay.

24 On page 68, the issue of withdrawn experts is  
25 mentioned. I'm going to stand by my ruling in Docket 10382.

11:34:29 1 If it's an expert that the defendants have withdrawn,  
2 plaintiffs can present it if the expert is unique and the  
3 evidence is not cumulative.

4 With respect to the Stein deposition, Dr. Stein,  
11:34:43 5 S-T-E-I-N, on page 68, the question I have for plaintiff's  
6 counsel is, do you want to present Dr. Stein in your case in  
7 chief?

8 MR. O'CONNOR: We understand they're calling  
9 Dr. Stein, so based upon that I don't think we need to put  
11:35:09 10 anything in in our case from Dr. Stein's deposition.

11 THE COURT: You'll just cross-examine him live?

12 MR. O'CONNOR: Yes.

13 THE COURT: Okay. That resolves that issue.

14 MR. LOPEZ: Your Honor, before you move on, I don't  
11:35:20 15 want to forget this. I flagged it, page 13, line 24. We  
16 allowed the word "approval" to be put in this pretrial order,  
17 and it should say "clearance." Could we just make that  
18 correction before the final pretrial order.

19 THE COURT: This is plaintiff's contention where you  
11:35:43 20 said it received FDA approval?

21 MR. LOPEZ: Yes, Your Honor. Line 23 and onto 24.

22 THE COURT: All right. We'll deem that as changed  
23 from "approval" to "clearance."

24 MR. LOPEZ: Thank you.

11:36:04 25 THE COURT: There's really nothing, I suppose, to

11:36:06 1 decide on this, but I have to say that when you indicated at  
2 some point that you were really zeroing in on the relevant  
3 exhibits and shortening the exhibit list, I didn't expect to  
4 receive more than 8,000 exhibits listed in the case between  
11:36:19 5 the two sides; 4,498 from plaintiff and 3,626 from defendants.

6 MR. COMBS: Your Honor, if I may. We're still  
7 working on a list of 250 to 300 or so. We've asked -- we've  
8 had a meet and confer discussion with Bard on that and asked  
9 for their objections -- actually just asked for their  
11:36:45 10 objections to that list.

11 Bard sent back the full list. It was Tuesday  
12 morning, and so we just submitted that. But we still intend,  
13 Your Honor, at least on plaintiff's side, to have a culled  
14 list of 250 to 300 or so, which is a subset of those in Booker  
11:37:02 15 and also obviously new documents dealing with the Eclipse and  
16 other issues.

17 THE COURT: All right.

18 Anything else on the final pretrial order?

19 MR. NORTH: Your Honor, I -- I'm not sure this is for  
11:37:17 20 the pretrial or afterwards, but there was some discussion at  
21 the April 13 hearing, my understanding is, about them  
22 disclosing to us a subset of almost 20-plus corporate  
23 witnesses that they have we've accepted subpoenas for, as to  
24 which ones they are really going to call, and we would like  
11:37:35 25 some guidance on that.

11:37:37 1 MR. O'CONNOR: Well, Your Honor, I think we are close  
2 to telling them which ones. We received an e-mail from  
3 Mr. Lerner about the availability of specific witnesses. I  
4 can tell you it's less than 20. I think by early next week we  
11:37:52 5 will be able to tell them, defense, who we want and when we  
6 want.

7 And I have one other issue I'd like to raise on  
8 witnesses.

9 THE COURT: Before you leave that subject, I'm going  
11:38:04 10 to require you to get that information to them by the close of  
11 business on Tuesday, the 8th, so they've got it a week ahead  
12 of time as to who you want to respond to the subpoenas.

13 MR. O'CONNOR: And we can handle that.

14 One witness that I have talked to Mr. North about is  
11:38:22 15 Ms. Raji-Kubba. Very important to the Eclipse case. She was  
16 with research and development here in Tempe. What we've been  
17 told is that she's relocated in Bard to somewhere else.

18 Mr. North and I have talked about whether she could  
19 come to Phoenix, and I suggested to him that we may file a  
11:38:41 20 Rule 43 or ask guidance from you about Rule 43. In other  
21 words, have her appear in court from somewhere, an off  
22 location, and I would just draw the Court's attention to  
23 Rule 43. And we have talked about it. Mr. North has been  
24 kind enough to tell me he was going to get back to me, and  
11:39:02 25 that's just one issue I think that if we could get close to

11:39:06 1 resolving, that would be helpful to us.

2 THE COURT: Mr. North?

3 MR. NORTH: Your Honor, we have a number of problems  
4 with this particular situation. First of all, it's my  
11:39:14 5 understanding that Ms. Raji-Kubba is not under subpoena, and I  
6 was not authorized by the company to accept service for her.

7 The second thing is she has -- she worked in  
8 Minneapolis. She is the CEO in Minneapolis of another Bard  
9 division called Lutonix, which makes a drug eluting stent.  
11:39:39 10 She is the CEO there, she works there. She is going to be  
11 there part of the time of trial. And then she is supposed to  
12 have a business trip to Europe for some particular part of the  
13 time, and I think her availability -- and she's got a big  
14 business meeting at Becton Dickinson, the new company that  
11:39:59 15 bought Bard, during part of that. She has a lot of  
16 availability issues.

17 They took a five- or six-hour deposition of her, the  
18 same attorneys. They thoroughly questioned her. They  
19 presented the Court with designations for that deposition.  
11:40:11 20 And it seems to me that this is one that, under the rules and  
21 under fairness, also should be presented to the jury by  
22 deposition.

23 THE COURT: Have you subpoenaed her? Did you  
24 subpoena her?

11:40:24 25 MR. O'CONNOR: I don't believe we did because we were

11:40:25 1 told that she had relocated, and we had discussions about Bard  
2 making her available. I suppose we could send them a subpoena  
3 and try to get her under subpoena at this point.

4 THE COURT: Well, you can't subpoena her to come to  
11:40:40 5 Arizona; right? You can only make her go 100 miles.

6 MR. O'CONNOR: Right.

7 THE COURT: If you don't have her under -- if you  
8 didn't subpoena her while she was in Arizona so you can compel  
9 her to come to trial, I have no basis upon which I can compel  
11:40:56 10 her to come to trial.

11 Rule 43, as you know, is a very high standard. It's  
12 good cause and in compelling circumstances, then remote  
13 testimony can be given.

14 And it seems to me what you're in effect asking me to  
11:41:14 15 do, Mr. O'Connor, is compel defendants to make her go to a  
16 location where she could appear by video conference during the  
17 trial here; right?

18 MR. O'CONNOR: That's -- that's correct. And the  
19 reason we're asking that is because this is an Eclipse case.  
11:41:34 20 They know it. And they know how important she is to the  
21 Eclipse case. And to be perfectly honest, Your Honor, we  
22 weren't aware that she had left Tempe, Arizona until just  
23 recently.

24 THE COURT: Well, did you depose her?

11:41:46 25 MR. O'CONNOR: She was deposed in this case. I mean,

11:41:48 1 she was deposed in the MDL. But in view of rulings that have  
2 occurred, in view of the differences now in this Eclipse case,  
3 we think that she is absolutely material to put on. And, you  
4 know, we think that we do show some compelling reasons why she  
11:42:05 5 should be able to appear, and it would not be -- you know, we  
6 could make it very convenient for her and for counsel to do  
7 that.

8 MR. NORTH: Your Honor, I just want to be very candid  
9 with the Court because Mr. O'Connor, I think, has  
11:42:18 10 misunderstood, and I didn't want there to be any suggestion  
11 that I was misleading anyone.

12 Ms. Raji-Kubba does still maintain a residence in  
13 Phoenix, because she was at BPV for many years. She spends  
14 very little, if any, time, I don't know how much, but she's  
11:42:33 15 not there very often because she worked in Minneapolis. I was  
16 told -- well, first of all, they served her with a subpoena  
17 prior to Booker. They managed to serve her before Booker.

18 When we came in at the pretrial conference, I advised  
19 that she -- the very fact I'm advising now, that she now works  
11:42:49 20 in Minneapolis and asked them to play her deposition. At that  
21 point they agreed to do so.

22 I'm just saying that -- I know they suggest the  
23 situation is different now, but I don't want there to be any  
24 suggestion that I have somehow said she's never been in  
11:43:04 25 Phoenix recently or that they did not know long beforehand,

11:43:07 1 because they did from the last pretrial conference, that she  
2 works in Minneapolis now.

3 MR. O'CONNOR: Well, I'm not going to get in a debate  
4 about that. I'm not going to debate what Mr. North may or may  
11:43:22 5 have said or may have thought --

6 THE COURT: Talk into the mic.

7 MR. O'CONNOR: Oh, excuse me.

8 And I thought her subpoena was accepted in Booker,  
9 and since that time she has relocated, is what our impression  
11:43:41 10 was. Now, we could still get a subpoena if she lives here and  
11 get her served one way or the other, ask them to accept  
12 service. I did not understand she still maintained a  
13 residence here. And that may be my -- on me. But that's not  
14 how I understood it.

11:43:58 15 THE COURT: Well, here's the problem I have with what  
16 you're asking, Mr. O'Connor. One is she can be compelled to  
17 come to this trial if she's served within the subpoena area in  
18 Rule 45.

19 If she isn't served in Arizona with a subpoena, there  
11:44:24 20 is no basis for me to compel her to come here to testify.

21 There is no other rule that I'm aware of that allows  
22 me to compel Bard to make her go to a courthouse in  
23 Minneapolis to appear by video. The compelling reasons  
24 language in Rule 43 is not for getting a witness to appear for  
11:44:43 25 video. It is for the very unusual circumstances where you

11:44:47 1 have a witness appearing in court by video rather than live.  
2 That's what compelling circumstances is addressing. So I'm  
3 not aware of any authority I have to order the defendants to  
4 make a witness go to a courthouse in Minneapolis so that you  
11:45:04 5 can present her by live video in Phoenix.

6 Are you aware of any authority for that?

7 MR. O'CONNOR: No, I'm not. No, I'm not. But now  
8 that we are aware there may have been some misunderstanding  
9 here, I suppose we can try to serve her one way or the other  
11:45:17 10 here in Arizona or ask Mr. North to accept it and go that  
11 route.

12 MR. LOPEZ: Your Honor, can I make one point about  
13 that? She wasn't -- they accepted service on her behalf in  
14 the Booker case.

11:45:28 15 Correct?

16 MR. NORTH: No. She was served at her home in  
17 Phoenix.

18 MR. LOPEZ: Okay. But wasn't she someone that was  
19 under your control that you were going to produce? Didn't you  
11:45:36 20 send us a letter and say this was a witness that we would work  
21 through you to make available to us in the Booker trial if we  
22 needed it? I believe you did with all Bard employees.

23 So, Your Honor, if that's the case, I mean, I think  
24 we were -- not that we're misled, but I think we were relying  
11:45:54 25 on counsel's good faith that this witness was under their

11:45:56 1 control. We didn't subpoena everybody. When we started  
2 subpoenaing, he said they would start accepting subpoenas for  
3 these people. But now she's allowed to leave the state before  
4 we can -- they should have told us --

11:46:07 5 THE COURT: Mr. Lopez, you didn't serve her with a  
6 subpoena for this case; correct?

7 MR. LOPEZ: I understand. But you have to understand  
8 that they were accepting subpoenas for their --

9 THE COURT: Well, they say they didn't accept for  
11:46:16 10 her.

11 MR. LOPEZ: Not for her, but they -- we started a  
12 different practice once they said they were going to accept  
13 subpoenas.

14 THE COURT: Mr. Lopez, look, the simple fact is there  
11:46:25 15 has been no subpoena served on that witness in Arizona that  
16 can allow her to appear in this courtroom under Rule 45(c).  
17 That hasn't happened.

18 MR. LOPEZ: Okay. I understand.

19 THE COURT: Since that hasn't happened, I can't force  
11:46:36 20 her to come.

21 MR. LOPEZ: Well, okay. I understand that. But I'm  
22 trying to give you the historical background here. They were  
23 accepting subpoenas for witnesses like Ms. Raji-Kubba. We did  
24 not subpoena her. That's why we didn't subpoena -- we didn't  
11:46:51 25 subpoena anybody because they were accepting service. Now

11:46:53 1 she's gone, we can't subpoena her. We're offering an  
2 alternative to the fact that we weren't advised that they were  
3 no longer going to be accepting --

4 THE COURT: What is the alternative?

11:47:02 5 MR. LOPEZ: To allow us to take her deposition by  
6 videotape within a different location.

7 THE COURT: You took her deposition.

8 MR. LOPEZ: Not deposition. Her trial testimony.

9 THE COURT: I don't have any authority to compel her  
11:47:11 10 to go to a courthouse in Minneapolis to appear in this trial.  
11 Unless you can cite me a rule that allows me to do that, that  
12 is not contemplated. If she is outside of the subpoena  
13 jurisdiction of this Court, she can appear by deposition.  
14 That's the way civil litigation has worked for the last 50  
11:47:27 15 years.

16 MR. LOPEZ: I understand, Your Honor, but I repeat,  
17 we were told we didn't have to subpoena their witnesses in  
18 this process. We were told that we just had to subpoena them  
19 and allow them to produce these witnesses. If she was going  
11:47:42 20 to be someone all of a sudden, after Booker, they were going  
21 to all of a sudden say that's not part of the deal because now  
22 she's in Minneapolis, then they should have just told us that  
23 and we would have had somebody, you know, maybe waiting  
24 somewhere where she might have been in her location here --  
11:47:56 25 that would have been worse for her. She would have had to

1 stay here for a week maybe for us to call her as a witness.

2 THE COURT: Mr. Lopez, I understand everything you're  
3 saying, but I haven't heard a citation to a rule that allows  
4 me to force her to go to a courthouse in Minneapolis.

5 MR. LOPEZ: Well, okay.

6 MR. O'CONNOR: I suppose since now we know she's  
7 here, and there's no misunderstanding there, we can have her  
8 subpoenaed or they can agree to accept a subpoena, then we can  
9 work that out.

10 THE COURT: You absolutely can ask them to accept a  
11 subpoena --

12 MR. O'CONNOR: Will you accept --

13 MR. NORTH: As I --

14 THE COURT: Hold on. We're not going to do that now.

15 You can ask them. If they say no, and you can serve  
16 her in Arizona, then I've got jurisdiction to make her come to  
17 trial. But if that doesn't happen, you're going to have to  
18 use her deposition. That's the way the rules work.

19 MR. LOPEZ: Well, you're not going to -- I mean, I  
20 think you have jurisdiction to impose or make counsel live up  
21 to the stipulations and agreements they've made with respect  
22 to this MDL and the appearance of witnesses. That's been the  
23 standing agreement and protocol and stipulation with them, not  
24 only in this case, in other cases. And they've agreed that we  
25 don't have to go door to door and wait outside a place of

11:49:07 1 business or a restaurant or something to subpoena people, that  
2 they would accept service.

3 They should have told us they were not going to  
4 accept service for Raji-Kubba. We have a stipulation from  
11:49:18 5 them that we do not have to serve the people that are under  
6 their control, and now they're not stipulating to it. I think  
7 you have the authority to impose that stipulation and  
8 agreement.

9 MR. NORTH: Your Honor, I just want the record to be  
11:49:28 10 clear that I specifically advised Mr. O'Connor via e-mail that  
11 I was not -- several weeks, a couple, three weeks ago, that I  
12 was not authorized to accept service on behalf of  
13 Ms. Raji-Kubba.

14 MR. LOPEZ: And he also told us for the first time  
11:49:44 15 today she has a residence in Arizona.

16 THE COURT: Mr. Lopez, stop. Please. Sit down. I  
17 understand what you've said. We're not going to continue  
18 this.

19 When did you send the e-mail?

11:49:53 20 MR. NORTH: I will have to look it up. I'm sure I  
21 can find it. At least two or three weeks ago.

22 MR. O'CONNOR: That was sent.

23 THE COURT: Okay. There's been time to try to  
24 subpoena her. I'm not going to -- if that was communicated to  
11:50:04 25 her two or three weeks ago, that was a month before trial,

11:50:07 1 three weeks before trial, that's time to subpoena her.

2 We're finishing the discussion now. I'm not going to  
3 force her to come here unless you subpoena her. And that's  
4 basic civil procedure 101. That's what Rule 45 says.

11:50:22 5 And you've got her deposition. So you can show her  
6 deposition.

7 All right. Anything else we need to address in the  
8 final pretrial order?

9 MR. STOLLER: I don't think so.

11:50:40 10 THE COURT: Plaintiff's counsel, anything else you  
11 want to raise?

12 MR. O'CONNOR: Nothing on our side.

13 MR. NORTH: Very minor housekeeping thing,  
14 Your Honor. I was talking to Nancy beforehand. Would the  
11:50:48 15 Court have any objection during the Jones trial if I add a  
16 little TV tray or something that I put next to the podium when  
17 I'm doing a lengthy direct examination to keep my exhibits on?  
18 I felt like I was having to bend down in a box to get them  
19 many times.

11:51:04 20 THE COURT: That's fine.

21 MR. LOPEZ: Did he say TV tray?

22 MR. NORTH: I guess that's a southern term, but yes.

23 MR. LOPEZ: You mean one of those little plastic  
24 things that fold like that?

11:51:17 25 THE COURT: You can bring your own TV tray, too, if

11:51:19 1 you want.

2 I am going to adopt the final pretrial order. It  
3 will now be controlled by Rule 16(e), which, as you know,  
4 means it can only be changed to avoid manifest injustice.

11:51:35 5 All right. Let me talk about a few minor matters.

6 Please remember when we get to opening statements  
7 that they're not arguments. I thought both sides did a good  
8 job of that in Booker, but I just want to raise it again so we  
9 don't lapse into argument in the Jones case.

11:51:50 10 I'm assuming the rule of exclusion of witnesses is  
11 being invoked; is that right?

12 MR. NORTH: Yes, Your Honor.

13 MR. O'CONNOR: Yes.

14 THE COURT: Okay. We'll take the same approach we  
11:51:57 15 did in Booker; advise your own witnesses of that fact.

16 MR. STOLLER: Your Honor, on that, on the rule, I  
17 think we did it last time in Booker that we're not applying  
18 that to experts?

19 THE COURT: That's right.

11:52:10 20 Counsel from Gallagher & Kennedy, would you please  
21 send documents to our office in Word format. We have asked  
22 over and over and we keep getting them in rich text format.  
23 And when they come in rich text format, we've got to go  
24 through about a ten-step process to convert them to a Word  
11:52:28 25 document.

11:52:29 1 Nancy tells me she has asked that about a dozen  
2 times, and she keeps getting rich text format documents. So  
3 going forward, send them in Word, please.

4 MR. STOLLER: Understood. Let me make sure I'm clear  
11:52:42 5 on this, because we actually operate on a Word system, so  
6 we're probably sending you a later version of Word than what  
7 the Court has and you're -- and it is being converted.

8 THE COURT: We've got a current version of Word.  
9 It's a different kind of document you're sending. But -- and  
11:52:57 10 when she raised it for the fourth or fifth time, somebody from  
11 your office called the IT department to tell them to come up  
12 and tell her to start accepting them. You shouldn't be going  
13 around her on this. Work it out and get her a Word document  
14 that we can just open. That is not a hard thing to go.

11:53:16 15 MR. STOLLER: Okay, Your Honor.

16 THE COURT: It has been raised many times without  
17 success. And yesterday we got rich text documents, and I  
18 watched her go through the ten-step process to convert them to  
19 a Word document. So please work that out.

11:53:28 20 MR. STOLLER: We will, Your Honor. I'll find out  
21 what's happening.

22 THE COURT: And both sides, when it comes, there was  
23 some difficulty in the Booker trial with the electronic form  
24 of the exhibits that Traci was getting to use them on the JERS  
11:53:41 25 system that we use. Please make sure we get them to her in

11:53:45 1 the right format so we can just get them loaded and get them  
2 to the jury at the end of the trial. Those are all minor  
3 matters.

4 All right. The only other issue that I have on my  
11:53:58 5 list that we need to talk about is the issue that I identified  
6 in the motion to reconsider the cephalad migration deaths.  
7 That is the question whether removing all references to death  
8 will somehow impair the plaintiff's ability to present their  
9 case.

11:54:18 10 Before we go to that, are there other matters that  
11 either side wants to raise?

12 MR. O'CONNOR: Nothing from the plaintiff.

13 MR. NORTH: Nothing from the defense, Your Honor.

14 THE COURT: All right.

11:54:50 15 Counsel, I have a 1:30 naturalization ceremony, and  
16 so I'd prefer not to break for lunch until 1:00, and then come  
17 back and do it, because we'll just have to interrupt it if it  
18 goes more than a half hour for me to go down and do that  
19 swearing in of citizens. So I think I'd like to just push  
11:55:09 20 ahead and deal with that issue now.

21 But we need to take a break for the benefit of the  
22 court reporter. So are you all right on us taking a 15-minute  
23 break and then coming back and addressing that issue?

24 MR. STOLLER: Yes, Your Honor.

11:55:24 25 MR. NORTH: Yes, Your Honor.

11:55:24 1 THE COURT: Okay. We'll be back at 1:10.

2 THE COURTROOM DEPUTY: 12:10.

3 THE COURT: 12:10.

4 (Recess taken from 11:55 to 12:14.)

12:14:36 5 THE COURT: All right. Counsel, the purpose of this  
6 discussion, as you know, is for me to decide whether some  
7 references to Recovery filter cephalad migration deaths should  
8 be included in the material in order to make it  
9 understandable.

12:14:52 10 I received a stack of exhibits about 20 minutes  
11 before the hearing started, so I haven't looked at them. I  
12 assumed you were sending them over so I'd have a copy to look  
13 at as we talked through them.

14 Plaintiffs, I think it's up to you to make whatever  
15 showing you choose, so I'm happy to hear what you have to say.

16 MR. LOPEZ: Your Honor, I'm going to handle this part  
17 of this.

18 MR. STOLLER: Okay. Go ahead.

19 THE COURT: That's fine.

12:15:17 20 MR. LOPEZ: Okay if I come to the podium?

21 THE COURT: Yeah.

22 MR. LOPEZ: I'm focusing on the Court's order where  
23 you asked us to show evidence where the plaintiffs may be  
24 seriously hindered in presenting her claims. Page 6,  
12:15:36 25 Docket 10920.

12:15:40 1 As the Court knows from the prior trial that one of  
2 the issues in the case, and maybe could be the most important  
3 one, we don't know, is whether or not the Recovery filter was  
4 an appropriate predicate device for the G2 filter. In fact,  
12:15:57 5 we have experts that talk about that and, in fact, we have  
6 their own expert, I think Dr. Tillman talked about it, and  
7 some of their lay witnesses talked about if the Recovery  
8 filter was not a legally marketed device, in other words, if  
9 it was adulterated, it was an inappropriate predicate for the  
12:16:13 10 G2, which would have -- just by that fact would have made the  
11 G2 an illegally marketed device.

12 So we need to be able to fully establish and have an  
13 ability to fully develop that evidence at trial.

14 And whether or not the Recovery filter was  
12:16:40 15 adulterated or misbranded may depend on one migration or may  
16 depend on whether or not there was one, two, several deaths as  
17 a result of the Recovery filter.

18 These are a family of devices. There's no doubt  
19 about that. All of these devices were borne out of the  
12:17:04 20 Simon Nitinol filter, and ultimately the retrievable devices  
21 were borne out of the Recovery device. In fact, I think it  
22 was Dr. Altonaga said that, in essence, these all relate back  
23 to the Simon Nitinol filter with respect to substantial  
24 equivalence.

12:17:23 25 One of the most significant factual events with

12:17:26 1 respect to whether or not the Recovery filter was adulterated,  
2 misbranded, or performing substantially equivalent to the  
3 Simon Nitinol filter was Natalie Wong's fatality --  
4 statistically significant analysis of fatalities.

12:17:45 5 The Court will recall that, I think it was May of  
6 2004, there had already been one death by then, and then a  
7 second death where she did a second analysis, and it was  
8 determined by that analysis that there was a statistically  
9 significant difference in fatalities between the Recovery  
12:18:04 10 filter and the Simon Nitinol filter and a number of other  
11 devices. So there's two issues there, Your Honor.

12 Number one is it's been established that the Recovery  
13 filter is not performing in a manner in which it's being  
14 represented, certainly in its marketing material, as being a  
12:18:22 15 device that is as safe and effective as competitors, and maybe  
16 better. That makes it misbranded. As soon as you say  
17 something that isn't true in your marketing, you've misbranded  
18 your device. When you misbrand your device, it is illegal.  
19 You are now illegally marketing it until you bring it within  
12:18:40 20 compliance.

21 There's no question that once you compare those  
22 fatalities to the history of the Simon Nitinol filter that it  
23 is adulterated, and that it is plaintiff's position, and our  
24 experts, Dr. Parisian in this case, will testify that it is no  
12:19:01 25 longer a legally marketed device and was an inappropriate

12:19:06 1 predicate for the G2.

2 And since the G2 was -- I know these are technical  
3 regulatory issues, but we're in that world. We're in the FDA  
4 world, we're in the world of federal regulations.

12:19:18 5 Moreover, Your Honor, the IFU from the Recovery  
6 filter was never changed. Never changed to incorporate the  
7 fact that -- not that filters cause death, but that the  
8 Recovery filter caused 19 deaths before the G2 filter was on  
9 the market.

12:19:37 10 Customarily, in the custom and practices, when you  
11 have another 510(k) product that's put on the market you  
12 generally adopt, and I think you'll see evidence here, at  
13 least from the Recovery to the G2, there's the same IFU.

14 So there's evidence here that maybe the IFU should  
12:19:59 15 have adopted -- and we have a right to make that part of our  
16 case. In other words, these are part of our claims. The IFU  
17 does not tell the story with respect to the warnings about the  
18 Recovery filter.

19 And, again, it's in the same family of devices. We  
12:20:11 20 have a right to put before this jury that the G2 IFU and the  
21 warnings and precautions were inadequate and they should have  
22 described the death history, the fatality history of the  
23 Recovery filter, which would have had to been adopted by the  
24 G2 and, in this case, the Eclipse filter, which was basically,  
12:20:31 25 by their own testimony of their own witnesses, a G2 device.

12:20:38 1 That's our biggest concern. Our biggest concern is  
2 our inability to develop an important counter to the FDA  
3 presence in this case pursuant to the Court's ruling on that  
4 issue. And that is, is there a violation of a federal  
12:20:56 5 regulation about selling an adulterated product? There is no  
6 one point in time where a jury may believe that's the case or  
7 whether an expert may believe that's the case. But we do know  
8 that as of May of 2004, where Natalie Wong did her  
9 statistically significant analysis of fatalities, there was no  
12:21:17 10 question that this company had evidence that they were selling  
11 an adulterated product because it was no longer performing, as  
12 their experts have said. It has to maintain substantial  
13 equivalence throughout the life of the device.

14 We don't have any other analysis. We don't have an  
12:21:34 15 analysis of fractures, of just migration.

16 And now we get to December of '04, where Dr. Lehmann  
17 does a similar analysis and does a comparison not only with  
18 competitors but with the Simon Nitinol filter. And, again, we  
19 have more evidence where it's included in the HHE. Fractures,  
12:21:56 20 migrations, perforations, and death are four to five times  
21 greater and are statistically significant and consistent with  
22 the internal bench testing of the company.

23 The other issue, Your Honor, is, and this goes to the  
24 issue of punitive damages, we -- not only in the crisis  
12:22:18 25 communication plan, but we got testimony, I can't remember

12:22:21 1 what witness it was, how important maintaining a reputation it  
2 is for a company for one product because if you lose that  
3 reputation, if you have bad press on that device, it could  
4 affect how physicians and customers see your other devices and  
12:22:44 5 whether or not they have not only confidence in that product  
6 and its subsequent iterations, but whether or not the  
7 company -- whether customers have confidence in the company's  
8 other products.

9 The fact that they would not reveal the nature and  
12:23:02 10 extent of how dangerous and, frankly, deadly the Recovery  
11 filter was, the company was motivated to keep that out of the  
12 potential customers for the G2. I think that's an important  
13 part of why there should be punitive damages and the  
14 motivation behind their whole development of the G2 and  
12:23:20 15 eventually the Eclipse.

16 So one other thing they decided that there was not a  
17 clinical trial necessary for the G2. We know there wasn't. I  
18 mean, there was -- at least there was a clinical trial for the  
19 Recovery filter.

12:23:39 20 We should be able to address this jury and present  
21 evidence that it was based on the history with the Recovery  
22 filter. How incredibly unreasonable it was that they put out  
23 another device only having done bench testing, less bench  
24 testing and less animal testing than they did with the  
12:24:00 25 Recovery filter, and let's just see what happens.

12:24:03 1 I mean, I find that as something that we should be  
2 able to tell the jury that, wouldn't you think, in view of the  
3 history that this company had with its predicate device, with  
4 the device that they were redesigning, to now put out in the  
12:24:17 5 open public after it had 19 deaths that they should have done  
6 anything other than to just stop and let's see if the G2  
7 really works.

8 Now, did it help with cranial migrations and deaths?  
9 It did. But what did it do? It created a whole new  
12:24:39 10 constellation of problems that were potentially deadly. I  
11 mean, every witness, Dr. Ciavarella, other of their witnesses  
12 agreed that caudal migration is not a migration to the heart,  
13 but you're exposing a patient to not only death, but now  
14 you're exposing a patient to not having a device that will  
12:25:01 15 even work because it tilts so significantly, as we saw in the  
16 EVEREST trial.

17 I just don't know how we try this case when all of  
18 this information about the Recovery filter is so intertwined.  
19 And Mr. Stoller is going to give you some examples of that.

12:25:15 20 But I think the points I'm trying to make here,  
21 Your Honor, are very important, and they do seriously hinder  
22 plaintiff's presentation of her claims, of her failure to warn  
23 claim. Why is that not in the IFU? It should be. It's our  
24 position that the IFU is deficient and that it's customary  
12:25:32 25 and -- it's custom and practice for 510(k) devices to adopt

12:25:39 1 the prior IFU. And that should have included those 19 deaths.

2 The other thing is, and we've made this motion  
3 before, we're going to hear about how filters save lives.  
4 It's in their opening statement. No matter what evidence

12:25:56 5 comes in in this case with respect to the fact that the  
6 medical literature would suggest that we really don't know and  
7 that the trending is that they probably don't, we're going to  
8 hear that. And we're going to be -- not be able to establish  
9 that these things could actually cause people to lose their  
12:26:13 10 lives, and that the device upon which -- plus, we don't know  
11 everything about how these devices perform. We know that  
12 because there's underreporting.

13 We do see evidence -- I know you distinguished those  
14 in your order, Your Honor, but the truth is that the Eclipse  
12:26:30 15 potentially could have caused the same consequences as the  
16 Recovery filter. It was only on the market for a short period  
17 of time.

18 THE COURT: Mr. Lopez, other than the reference to  
19 the Wong report and the Lehmann report, it sounds to me like  
12:26:43 20 you're rearguing the issue I decided, whether cephalad  
21 migration deaths should be admitted. It seems to me you're  
22 arguing I should change my previous ruling and just let in all  
23 of the cephalad migration death evidence.

24 MR. LOPEZ: Well, no, I'm giving you -- you asked --  
12:27:02 25 I thought the question before the Court and for us to address

12:27:05 1 today is whether omitting that evidence would seriously hinder  
2 plaintiff's presentation of her claims.

3 THE COURT: Well, if you're saying -- the idea was to  
4 get specific exhibits where if you take out a reference to  
12:27:21 5 death you can't present the evidence effectively. You're  
6 arguing broadly that she can't present her case effectively  
7 unless I let in all the death evidence.

8 MR. LOPEZ: Well, okay. I am. I'm doing that to  
9 advocate for what I think should be the ruling, but I've given  
10 you two pretty significant examples, maybe more than --  
11 probably more than two. And that is the fact that it really  
12 hampers our warnings claims and, more importantly, it hampers  
13 our ability to establish that the Recovery filter, through  
14 evidence by this company, Natalie Wong's analysis of a  
12:27:56 15 statistically significant increased risk of fatalities existed  
16 in comparison to the Simon Nitinol filter, and therefore they  
17 needed to stop. The federal regulations say you should have  
18 stopped.

19 And then, of course, Dr. Lehmann's references in the  
12:28:11 20 HHE in the RAP. And I know Mr. -- like I said, Mr. Stoller  
21 has other examples of that.

22 THE COURT: Is he going to talk about those two  
23 exhibits?

24 MR. LOPEZ: I think -- I believe so.

12:28:23 25 MR. STOLLER: I will, Your Honor.

12:28:23 1 THE COURT: Okay.

2 MR. LOPEZ: So I'm going to pass to Mr. Stoller --

3 THE COURT: All right.

4 MR. STOLLER: Good afternoon, Your Honor. My job is  
12:28:38 5 to walk you through, hopefully, the specific examples that we  
6 have provided with respect to how this evidence is, we think,  
7 inextricably intertwined with the evidence that we intend to  
8 present in support of our claims here.

9 And let me start with the exhibits that you just  
12:28:55 10 discussed with Mr. Lopez, and, in particular, we gave you  
11 three transcripts, Your Honor, one for Mr. DeCant, one for  
12 Mr. Ganser, and one for Mr. Orms, to give you a little  
13 guidance. I'm not going to go through the whole thing.  
14 There's a fair amount of testimony there. I'm going to point  
12:29:14 15 some specific spots along the way, but the particular -- and  
16 we gave you six exhibits also, Your Honor.

17 And the particular exhibit that Mr. Lopez was just  
18 referring to with respect to this issue as to the significant  
19 difference found is what is Trial Exhibit 2243.

12:29:34 20 And you'll see, Your Honor, there at the top of it is  
21 an e-mail. Once you get past the cover page of the exhibit is  
22 an e-mail from Doug Uelmen. But if you dig down to actually  
23 the bottom of the second page of the exhibit itself and the  
24 top of the third page, that's the evidence that Mr. Lopez was  
12:29:54 25 just talking about in terms of the finding of a significant

12:29:57 1 difference between the Recovery and the SNF, which is,  
2 obviously from our perspective, a very important piece of  
3 information in talking about the issue of whether or not this  
4 filter, the Recovery filter and the subsequent devices that  
12:30:14 5 rely on it as its base predicate, were adulterated and  
6 misbranded and should have been taken off the market.

7 This is dated, Your Honor, April of 2004. It's after  
8 the first few deaths. The reference there, the document  
9 there, there is discussion of death in the document. And  
12:30:39 10 defendants -- we submitted this to defendants. They provided  
11 us some back and said, hey, we suggest some redactions that  
12 might fix the problem. This is not one of those. They think  
13 that this document can't come in at all.

14 And one of the significant points, Your Honor, in  
12:30:52 15 addition to Ms. Wong's finding that there is a significant  
16 difference, which goes directly to the heart of our claim  
17 about why this product should have been taken off the market,  
18 is, if you look at the next page there's an e-mail that has at  
19 the bottom Bates label 75, Your Honor, there's an e-mail from  
12:31:11 20 Dr. Lehmann, and he addresses the issue of why they're loo- --  
21 particularly they're looking at deaths here. Why are we  
22 making an analysis of death as opposed to other things?

23 And what Dr. Lehmann says in the very last paragraph  
24 of that page, and I'm just going to read it into the record.

12:31:24 25 "I believe that the underreporting of nonsignificant

12:31:27 1 migrations will be so extreme that calculating a proportion of  
2 migrations that are fatal based on MAUDE data will be entirely  
3 suspect. We should stick to the much more likely to be  
4 reported event of filter associated death compared with  
12:31:40 5 estimated sales. This also has the best clinical relevance  
6 for practitioners."

7 They are relying -- that is Bard saying we need to  
8 look specifically at the death evidence to see, is our filter  
9 performing consistent with our expectations, with the market,  
12:31:56 10 and with our predicate device?

11 That can't be extracted, Your Honor. That is crucial  
12 to the finding they're making that, no, it's not. There is a  
13 significant difference for the Recovery filter.

14 This comes up, Your Honor, to -- and I don't want to  
12:32:11 15 make you flip back and forth too much, but it comes up in the  
16 testimony of Mr. Ganser when he discusses this document. In  
17 particular, and I'll just direct you to the pages and I'm sure  
18 you'll read these when you get the time, but 130 to 133 is his  
19 discussion of the document.

12:32:30 20 To orient you, Your Honor, in the transcripts, and we  
21 provided -- again, we provided these to the defense, they sent  
22 back and suggested here's some redactions we think that cure  
23 the issues. And in fairness, we took out some. We said,  
24 okay, we agree, we'll withdraw certain of the designations in  
12:32:49 25 here because we don't think they're necessary to reference the

12:32:52 1 death in that way or at that point in time. But the others,  
2 we don't.

3 And what we've done, Your Honor, to help you see what  
4 they're proposing in terms of the redactions, it's highlighted  
12:33:05 5 in yellow -- I'm sorry, in green. Anyplace you see green is  
6 a proposed redaction.

7 In Mr. Ganser's deposition, the yellow highlighting  
8 are our designations, the blue is theirs, the green is where  
9 they've proposed to take the evidence out.

12:33:19 10 But even looking here, Your Honor, page 130 to 131,  
11 and I'm not going to read page/line of this, what they're  
12 comparing there is a statistically significant evidence of  
13 increased risk of death. They're not looking at increased  
14 risk of other things. This is a very particular and specific  
12:33:35 15 analysis they're doing.

16 And if you take out, as they suggest here on page  
17 130, well, let's delete and remove "of death," and they've  
18 said, well, we've played the videos and it sounds seamless, I  
19 don't know whether that is true or not, but that is not asking  
12:33:53 20 the same question. It's asking them, "Because we have a  
21 statistically significant evidence of increased risk  
22 generally." That's not the analysis they did. And they will  
23 tell the jury all kinds of things about how MAUDE data is  
24 unreliable and you can't look at those sort of things.

12:34:09 25 There is a very specific analysis that's going on

1 here and there is no reasonable way to extract it without,  
2 candidly, torturing the evidence into becoming something it's  
3 not.

4 The other --

12:34:20 5 THE COURT: This is talking about the Natalie Wong  
6 statistics?

7 MR. STOLLER: That reference right there in  
8 Mr. Ganser's deposition is the question and examination with  
9 respect to the Exhibit 2243.

12:34:37 10 The other documents, Your Honor, and let me point you  
11 then, also, Your Honor --

12 THE COURT: Hold on. Hold on just a minute,  
13 Mr. Stoller.

14 Go back to 2243.

12:34:56 15 MR. STOLLER: Yes, sir.

16 THE COURT: Look, if you would, at -- it doesn't have  
17 a Bates number but it's the chart after the page ending Bates  
18 number 76.

19 MR. STOLLER: Yes, sir.

12:35:36 20 THE COURT: What is failure rate?

21 MR. STOLLER: The answer is I can't tell you that. I  
22 don't know off the top of my head.

23 Mr. Lopez, Ramon, might know.

24 MR. LOPEZ: What's that?

12:35:52 25 MR. STOLLER: The chart at the back of that long

12:35:53 1 e-mail.

2 MR. O'CONNOR: Which e-mail?

3 THE COURT: It's 2243.

4 MR. STOLLER: Let me walk over to counsel table.

12:36:00 5 THE COURT: It's 2243. It's what is being  
6 transmitted, as I understand it, by Dr. Lehmann.

7 MR. STOLLER: Your Honor, there are two attachments  
8 to this e-mail. One is a product failure rate versus quarter,  
9 and one is a product statistical summary. To which are you  
10 referring?

11 THE COURT: To both.

12 MR. STOLLER: To both.

13 THE COURT: They're both measuring failure rate.

14 MR. STOLLER: So if you look at the e-mail,  
12:36:42 15 Your Honor, on page 1, which is this is what she is forwarding  
16 at that time, which is actually subsequent. If you look in  
17 the e-mail string, Ms. Wong's e-mail starts on page 3, and we  
18 go forward and she sends that to Mr. Uelmen.

19 And then on page 2, Mr. Uelmen responds, and asks, Is  
12:37:02 20 there a way to show this on an overhead and is there a way to  
21 predict what percent failure there would be deference -- I'm  
22 not sure, that must mean "difference" -- comparing it to  
23 OptEase.

24 And then she attached some PowerPoint charts and  
12:37:19 25 says, As to predicting percent failure, we can't make a

12:37:22 1 statistically valid statement since there's not enough data.  
2 But it's not clear what she's referring to at that point.

3 THE COURT: Well, that's what I'm wrestling with. I  
4 thought you had said all these charts and statistics were  
12:37:36 5 based on deaths. I thought that was the whole premise of what  
6 is the problem with --

7 MR. STOLLER: I'm saying her testimony is, and as is  
8 Mr. Ganser's and the others, this statistical analysis she did  
9 here, again, I start with the statement by Dr. Lehmann on  
12:37:56 10 page 4, is that what they're looking at here is the evidence  
11 of deaths. Specific to deaths because they find that "the  
12 underreporting of nonsignificant migrations will be so extreme  
13 that calculating a proportion of migrations that are fatal  
14 based on MAUDE data will be entirely suspect. We should stick  
12:38:12 15 to the much more likely to be reported event of filter  
16 associated death."

17 That then leads to Ms. Wong's e-mail on May 20th,  
18 2004, in which she finds in a 95 percent confidence interval  
19 there is a significant difference between Recovery and the  
12:38:31 20 SNF.

21 THE COURT: And these are not limited to deaths by  
22 cephalad migration; right?

23 Look at the bottom -- look at the bottom of page --

24 MR. LOPEZ: No.

12:38:44 25 MR. STOLLER: It's all --

12:38:45 1 THE COURT: All deaths; right?

2 MR. STOLLER: Yes. They're' evaluating how is the  
3 Recovery performing on that metric versus, again, competitors  
4 and its predicate device.

12:38:59 5 THE COURT: Let me ask this question, it's what I  
6 tried to tee up in the order that I entered: If it's true  
7 that what this document concerns is a statistical analysis of  
8 deaths by Recovery versus deaths by other filters, and you  
9 want to present it to show to the jury that the Recovery was a  
12:39:23 10 less safe product than the others to which it was being  
11 compared, and that Bard knew that, the question is what other  
12 evidence do you have of the fact that the Bard -- that the  
13 Recovery was a less safe product, it had more complications,  
14 Bard knew it, Bard went ahead and developed the G2?

12:39:52 15 In other words, if you can't present this exhibit,  
16 what do you have instead to show that the Recovery was a  
17 problematic filter and it led to the development of the G2 and  
18 cephalad migration was one of the problems?

19 MR. STOLLER: Well, we have other testimony that I'm  
12:40:16 20 going to go through in a moment that raises similar issues  
21 with respect to the death. As I think we indicated the last  
22 time I was here and we talked about this subject, that the  
23 investigations into the migration issues with respect to  
24 the -- with respect to the Recovery filter centered on death,  
12:40:33 25 and I'll walk you through in a moment --

12:40:35 1 THE COURT: So you are saying there is no other  
2 evidence of other measures or other statistics that were done  
3 regarding the Recovery, it's all death based analysis.

4 MR. STOLLER: I don't think that's accurate either.  
12:40:48 5 I think that there is -- but I don't think it's separated. In  
6 other words, there is not evidence that says we've looked at  
7 migrations and here's a statistical significant difference in  
8 the Recovery filter on migrations versus the market and versus  
9 the SNF, and that exists here in one pile.

12:41:05 10 And then there's a statistical analysis of fracture,  
11 and we've done an analysis of the Recovery and the competitor  
12 devices and the SNF, and here it is and here is a statistical  
13 difference here. And then tilt. And then perforation.

14 THE COURT: I'm getting the point. What I'm not  
12:41:25 15 getting is, let's say there's a basket of evidence that  
16 doesn't include death that shows the Recovery was a defective  
17 product, and there is a different basket of evidence that is  
18 based on death based analyses. The question I'm trying to  
19 answer is if I take away the death based basket how does  
12:41:45 20 that -- to what degree does that hamper your ability to show  
21 that the Recovery was a problematic filter that you think  
22 shouldn't have been on the market and led to the design of the  
23 G2? Without knowing what's in the other basket, I don't know  
24 how to make that determination.

12:42:01 25 MR. STOLLER: My point is there is not another basket

12:42:03 1 that separates them out. The other basket is by and large --  
2 let me find the exhibit number Your Honor, the HHE, that is  
3 Exhibit 1032.

4 I mean, this is the place where their analysis  
12:42:19 5 exists. I mean, this is where -- again, we can come in and do  
6 an outside analysis, but we want to prove they knew. What did  
7 they know? And what did they do when they knew it?

8 And Exhibit 1032, which has a couple of different  
9 depositions stamps on it, is the -- and I know you've seen  
12:42:42 10 this document before, Your Honor, in the summary judgment  
11 rulings and those sort of things and also at trial, but this  
12 is the December 17, 2004, HHE, which is where they recount the  
13 numbers that are found by their consultant, who is  
14 Dr. Lehmann, in terms of the comparative analysis he did. And  
12:43:01 15 he compares them on -- like I said, they're all together, and  
16 if you look particularly on what is page 2 of the HHE itself,  
17 under 2, that is where they report the consultant's analysis.

18 His reports to Bard go across death, filter  
19 migration, IVC perforation, and filter fracture. And he does  
12:43:22 20 them in one point. There's no -- other than what we just  
21 looked at with respect to the analysis by Natalie Wong, which  
22 is earlier in time, it's six, seven months earlier in time,  
23 that is also an important difference here, the fact that they  
24 knew much earlier than even this report that they're having a  
12:43:38 25 significant problem with deaths and that they're having a

12:43:41 1 statistically significant difference in this device versus its  
2 predicate and its competitors, should have compelled them to  
3 take action at that time and it was -- you know our contention  
4 is it never should have been on the market in the very first  
12:43:54 5 place, but certainly by that point, when they've now found  
6 there's a statistically significant difference between this  
7 device and the other, it should have come off at that point.  
8 These exist along a time frame, and so it's not the same to  
9 say, well, we can bring in --

12:44:08 10 THE COURT: I understand that point.

11 MR. STOLLER: -- 1032, but not the other one.

12 THE COURT: But sticking with Lehmann, if we look,  
13 for example, on Bates page 24, there's a couple of tables.

14 MR. STOLLER: Yes, Your Honor.

12:44:24 15 THE COURT: It looks in the first table as though  
16 there's reporting rates for adverse events, one of which is  
17 deaths, another of which is migration, another just fractures,  
18 et cetera.

19 And then there's a total at the bottom.

12:44:44 20 And the second table is similar.

21 I haven't read this document, so I don't know the  
22 context.

23 Tell me the difficulty that would occur if you took  
24 out the references to death from that document.

12:45:01 25 MR. STOLLER: In other words, if we just took a black

12:45:03 1 line through the word "death" and the associated statistics?

2 THE COURT: Yeah. If it was redacted.

3 MR. STOLLER: Well, I think it ignores one of the  
4 metrics that is important in the determination of whether or  
12:45:12 5 not this device is a reasonably equivalent device or a  
6 substantially equivalent -- excuse me, substantially  
7 equivalent device to its predicate and its comparison to other  
8 devices on the market.

9 In other words, what we're doing is we're trying to  
12:45:26 10 extract from Bard's mind what decision it made or should have  
11 made at the time based upon the available data.

12 If they had done an analysis that said, look, we have  
13 this frequency of migration, and then analyzed it in a vacuum,  
14 which they didn't do -- and I'll talk about that in a moment  
12:45:48 15 when we talk about Mr. DeCant's testimony -- if they'd done  
16 that in a vacuum and you had an isolated piece there to  
17 analyze, you could say, look, Bard analyzed these things  
18 independently and looked at them independently or should have  
19 looked at them independently, as opposed to the only way  
12:46:01 20 they've done it, which is they looked at it as deaths, and  
21 then deaths among other things. I think that there might be a  
22 way to talk about if -- and they came to a conclusion. We've  
23 concluded based on this piece of evidence that, standing  
24 alone, the perforation rate is such that this is not  
12:46:21 25 substantially equivalent, it's not an appropriate -- it's not

12:46:24 1 appropriate to treat it as a subsequent device and to use the  
2 SNF as a predicate, that might be a world in which we could  
3 talk about things in different silos. But it's never done  
4 that way.

12:46:38 5 And that's the fundamental problem with this, is that  
6 the only place that -- the only place this analysis ever  
7 happens is in the context of deaths. Because that's why  
8 they're focused on it. They're not so worried about any of  
9 this other stuff, candidly.

12:46:50 10 You don't have -- and, again, we're going to talk  
11 about this in a moment when we talk about some of these other  
12 exhibits and Mr. DeCant's testimony -- but they create a panel  
13 to review this stuff. But they're not -- they don't create a  
14 panel to review fractures, they don't create a panel to review  
12:47:04 15 perforations, tilt.

16 Their investigations and the teams they create center  
17 around and, candidly, only examine this in the context of,  
18 we're having deaths.

19 And even when we talk about -- and, again, we'll get  
12:47:18 20 to this in a moment -- but even when they talk about  
21 migrations, and they have this migration team, they only look  
22 at the deaths. The only time you see a remedial action plan,  
23 a failure investigation report, or an HHE is when there's a  
24 death.

12:47:31 25 And there are some reports -- and let me point you

12:47:34 1 for a moment to an example, Your Honor, and why we gave it to  
2 you as a difference.

3 Exhibit number 280. And I actually gave this to you  
4 to show you the difference between this and some of the other  
12:47:45 5 documents. This is an e-mail dated June of 2005. And it is  
6 an IVC Recovery filter adverse events executive summary. And  
7 you can look and see what it is, is this is numbers. We had  
8 43 filter migrations greater than 2 centimeters, and they  
9 break those down a bit. And then 12 of the 43 are deaths  
12:48:06 10 reported, and they break those down a bit. Then they talk  
11 about some other items. These are primarily looking at  
12 fracture migration.

13 This stuff, this -- let me tell you what's not here.  
14 No root cause analysis. No corrective and preventive action  
12:48:22 15 plan. No analysis whatsoever of what action to take. No  
16 containment.

17 Let me contrast that for a moment, Your Honor, to --  
18 let me just pick an example of the things we've given you.  
19 Exhibit 1014, which is a remedial action plan. And it says:  
12:48:45 20 BPV Recovery filter migration. Doesn't say death. But I'll  
21 tell you this is a death, as are each of the other ones we've  
22 given you in terms of the RAPs and the FIRs.

23 And they're investigating a death. And as you go  
24 through the pages, you'll see -- and there's a lot of stuff  
12:49:02 25 before you get there, but as you get to the end there are risk

12:49:05 1 assessments. If you look under what's bottom -- let's start  
2 at 85 on the bottom right-hand corner, which is a little deep  
3 into it, I think page 3 of the RAP itself.

4 There is an action plan. They've done some of --  
12:49:19 5 they've evaluated a bunch of evidence, you'll see above it,  
6 and then they have an action plan, and there's a bunch of  
7 items here. It's not necessary to go through all of them, but  
8 you can see there's a long, long list that extends onto page 4  
9 and to page 5, and all the way onto page 6. And among the  
12:49:36 10 things they address there are, what are we going to do?  
11 Right?

12 So if you go all the way to the bottom of page 4, now  
13 they come up -- okay, we're going to come up with migration  
14 categories to aid in our risk assessment. We're going to look  
12:49:49 15 at page 5, K, "Migration resulting in patient death requires  
16 the division PAT to convene immediately and initiate  
17 investigation per R002." So they're initiating a plan.

18 Under L, "Vena cava adverse event frequency rates  
19 will be reviewed on a quarterly basis." Now they're saying,  
12:50:10 20 well, we're going to review these -- they're taking actions  
21 and plans.

22 And if you look at the very last page of that, 6,  
23 product correction, says, "There's been no device, design or  
24 manufacturing problem that was identified as contributing to  
12:50:22 25 the death and no field action is recommended or required."

12:50:25 1 They undertake these investigations and -- and,  
2 again, these are just examples. There's about seven or eight  
3 of them along the way. But they're only taking them in the  
4 context of a death, and they only do anything in the context  
12:50:36 5 of a death. They mention the other migrations, they talk  
6 about the fact that there's been other migrations, but there's  
7 no analysis, there's no comparison, there's no, hey, what's  
8 happening here?

9 And, in fact, to take things a little out of order in  
12:50:50 10 terms of what I want to talk about, if you'll look at  
11 Mr. DeCant's deposition testimony -- and it's page 268 of the  
12 transcript we've provided --

13 Just whenever you're ready. Are you good?

14 If you see, we start our highlighting on line 14.  
12:51:22 15 And the testimony goes on over the next two and a half --  
16 about two pages.

17 This is my examination of Mr. DeCant. And I asked  
18 him, look, you are looking -- well, I'll just read the  
19 question and answer.

12:51:34 20 You recognized very early that there was a problem  
21 here; correct?

22 He says, Yes. We had a death -- I'm sorry, I'm  
23 summarizing, but, we had a death, so we wanted to really  
24 understand what could cause that death.

12:51:44 25 And then I asked him, you also had a number of other

12:51:47 1 migrations as well; correct?

2 Answer: Correct.

3 And those are the potential, as we discussed earlier,  
4 if they migrate to the heart of causing a death as well?

12:51:55 5 Answer: Yes. But those hadn't migrated to the  
6 heart, but we had a death, so then we wanted to deal with the  
7 death. We got a death now. It's a different issue.

8 And I asked him, it's a different issue because that  
9 person died as opposed to the other ones that didn't die?

12:52:09 10 Answer: That could be a different cause. Right.

11 I think there's supposed to be a question after him  
12 asking me.

13 But anyway, what caused one filter to only move  
14 2 centimeters and another one to go to the heart could be a  
12:52:22 15 totally different cause.

16 And then I asked him, a little further down the page,  
17 does any filter that migrates, that moves, have the potential  
18 ultimately to kill someone?

19 Answer: Not if it doesn't move to the heart.

12:52:32 20 I said, well -- excuses me -- what about is there a  
21 difference in the root cause of something that moves a filter  
22 2 centimeters versus into the heart?

23 Answer: It could be. I -- now that I'm sitting  
24 here, I don't have that knowledge today. It's been many  
12:52:45 25 years, but certainly at the time the logic would have been as

12:52:49 1 part of the process that's how we would have investigated. As  
2 a 2-centimeter migration, we would have thought differently  
3 than a migration that had gone to the heart.

4 And they never looked at that latter issue -- or  
12:52:59 5 excuse me, the former issue, Your Honor. There are no reports  
6 anywhere, no RAPs, no investigations that say, we've got --  
7 and you'll see these in some of the ones we've given you.  
8 Let's say we've got ten migrations of 2 centimeters or more.  
9 Or we have 14. It only comes up in the context of those  
12:53:16 10 documents investigating the death. And no analysis of them  
11 independent of them. None.

12 So the only place this investigation is going on into  
13 what's happening, why is this moving up, is related to deaths.  
14 And they make a distinction, they say, look, if it stops at  
12:53:33 15 2 centimeters, we look at differently because it may be a  
16 different cause.

17 And for us, that's the evidence that -- let me back  
18 up even further.

19 This evidence all starts with the question on the  
12:53:42 20 very first page we've given you of that deposition, at 249  
21 onto 250 of, do you recall that one of the significant changes  
22 that was made to the Recovery when you moved to the G2 was to  
23 widen the base of the Recovery filter?

24 Yes.

12:53:56 25 Question: Pretty significantly?

12:53:58 1 Answer: Yes.

2 And that one of the reasons you did so was to address  
3 this particular concern of migration, isn't it?

4 Answer: It was to address this large -- this concern  
12:54:06 5 of larger diameter cavas, yes.

6 Question: And migration in larger diameter cavas?

7 Answer: Sure.

8 We then talked about this investigation. It all  
9 centers on deaths.

12:54:19 10 The reason they changed the design to widen the  
11 base -- and it's significant, Your Honor. They go from a  
12 32-millimeter base on the Recovery filter to a 40-millimeter  
13 base on the G2, 25 percent increase in the difference, and  
14 they attribute it to all these migrations. But the only  
12:54:40 15 migrations they're looking at -- the only -- the only  
16 migrations they're looking at are those ones associated with  
17 the deaths.

18 And, again, part of my presentation was to walk you  
19 through some of these exhibits and show you, but you can do it  
12:54:57 20 on your own as well, that they never come to a root cause. I  
21 mean, that's the fundamental part tying back to our claim.  
22 Our claim is, Your Honor, they made a change, they made a  
23 pretty substantial change from the Recovery to the G2 in terms  
24 of widening the base that results in a lot of other issues  
12:55:13 25 that they didn't anticipate. And part of the reason is

12:55:16 1 because they never did a proper root cause analysis.

2 When you walk through these -- what were they doing  
3 at migrations, seeing the difference, what root cause analysis  
4 were they doing, what you'll see is -- and, again, if you look  
12:55:26 5 at some of the answers, well, they'll say -- well, let me  
6 point to a specific thing and then tell you what it actually  
7 means.

8 So if we look at --

9 THE COURT: I need to interrupt you, Mr. Stoller.  
12:55:35 10 You're running through a lot of evidence here and I'm  
11 understanding what you're saying, but I'm struggling with the  
12 basic idea or one of the basic ideas that led to my ruling on  
13 this issue.

14 It seems to me that what you are arguing is that this  
12:55:57 15 problem that Bard was focusing on which involved deaths caused  
16 Bard to widen the filter when it created the G2; the effect of  
17 widening the filter was to introduce new problems -- caudal  
18 migration, tilt, fracture, perforation -- and those problems  
19 carried through to the Eclipse.

12:56:23 20 So it seems to me the point you want to make to the  
21 jury is Bard widened the filter diameter without sufficient  
22 testing, without sufficient knowledge of what it would do, and  
23 introduced a problem that ultimately hurt Ms. Jones.

24 What I'm wrestling with is, it seems to me you can  
12:56:50 25 tell that story, that they widened the base, they widened it

12:56:55 1 to address cephalad migration, they didn't do appropriate  
2 testing, they didn't do a root cause analysis of the cephalad  
3 migration, they never tested it in patients, and it introduced  
4 all of these problems, one of which hurt Ms. Jones, without  
12:57:10 5 ever mentioning death.

6 That's what I'm wrestling with. It seems to me what  
7 you want to do is say they improvidently widened the base of  
8 the filter and introduced a problem that hurt our client.

9 And I'm still wrestling with the notion of why you  
12:57:29 10 can't say exactly that and have your experts explain why that  
11 was defective and the problems that G2 created were never  
12 resolved without mentioning death. It seems to me what you  
13 want to do is say, look, they're a really negligent company  
14 because it was death that spawned this improvident design.

12:57:51 15 MR. STOLLER: Well, one, I do want to say the latter,  
16 but that's not the issue I'm presenting to you today. The  
17 issue I'm presenting you today is the only evidence that gets  
18 to that piece of proof that they failed to conduct proper root  
19 cause analysis is in these documents that relate to the death  
12:58:05 20 investigation reports. It's the only place that analysis  
21 happens.

22 And what they do is, they say -- and, again, that's  
23 the point I was just going to get to. So let's take as an  
24 example the first of the -- I think it's the first of the RAPs  
12:58:20 25 I gave you.

12:58:56 1 Okay. Sorry, Your Honor. Exhibit 1014. On the  
2 fourth page.

3 It's among the list of the things that they did when  
4 they did their investigation and action plan in response --

12:59:11 5 THE COURT: Fourth page. What's the Bates number?

6 MR. STOLLER: 86 are the last two digits.

7 THE COURT: All right.

8 MR. STOLLER: Very top. Item number 4. This is  
9 their finding. This is their root cause analysis: "There  
12:59:22 10 were no design or manufacturing defects found to be associated  
11 with the filter."

12 That line, Your Honor, comes time and again in these  
13 reports. They say there's no problem with our filter. No  
14 design problem. Except that when you depose them -- and,  
12:59:35 15 again, this is the testimony of Mr. DeCant that I've put in  
16 front of you, what he says is, well, we didn't really find  
17 that. We didn't eliminate design as a problem, we just didn't  
18 have any evidence one way or another that it was.

19 And so the only way we can demonstrate that they  
12:59:47 20 didn't do proper root cause analysis is to say, okay, what  
21 analysis did you do?

22 Well, we did this.

23 What did you find?

24 Well, we found there was no design defect and we  
12:59:54 25 found -- and the other thing you'll see in these reports: Oh,

12:59:57 1 well, we found that they became overburdened by clot.

2 Which, by the way, was a risk that existed before.

3 They ignore doing the fundamental root cause analysis  
4 to why is this filter reacting in this way. And that's the  
13:00:15 5 only place that analysis happens, and the only way we can  
6 show, look, they didn't do what they were supposed to do, is  
7 to walk through these documents.

8 There's no other document -- I mean, there's no  
9 document that exists out there independent of these where we  
13:00:28 10 can say, look, here's what they did when they had problems  
11 with the Recovery filter; here's the analysis they did  
12 independent of it.

13 This is where the analysis resides. The only place  
14 the analysis exists are in these documents that are remedial  
13:00:45 15 action plans, failure investigation reports, and HHEs  
16 associated with the deaths.

17 So if you say -- the question is -- my question back  
18 is I don't know how I prove it without these documents. I can  
19 prove -- I can come and say they widened the base of it. That  
13:00:59 20 is undisputed. They did widen the base of it. I can say they  
21 did it in response to migrations, yeah.

22 And I can also talk about testing. But I can't talk  
23 about the root cause analysis, which is a fundamental aspect  
24 of our negligence claim, which is they did not act reasonably  
13:01:13 25 under these circumstances. They did not --

13:01:15 1 Here's why they didn't act reasonably, and it would  
2 be true if there weren't a death but it's particularly true  
3 when there is a death, which is, confronted with a device  
4 failure that in this case had a fatal effect but could have  
13:01:30 5 had a fatal effect, rather than drilling down and saying what  
6 is wrong with our design that it is doing -- having this  
7 reaction in these circumstances, they blame the circumstances,  
8 which exists for every filter on the market. And we don't  
9 have an ability to go and show, look, they come up with  
13:01:47 10 excuses, and the excuses come in many forms.

11 They say there is no design defect, but they have  
12 done no analysis of the design.

13 They say the device became overburdened with clots,  
14 but that is something that happens. Clots hit these things.  
13:02:03 15 That's what they're supposed to do. There is no analysis of  
16 the design.

17 In another one we've given you, they looked and they  
18 say, well, we don't really know. We don't have evidence of an  
19 autopsy that tells us anything.

13:02:12 20 It is excuse after excuse after excuse instead of  
21 addressing the problem that they should have been addressing.

22 That is central to our negligence claim, which is  
23 that they did not do what they were supposed to do when  
24 confronted with the problems they had. And that would exist  
13:02:26 25 regardless of death.

13:02:27 1 But the problem we have is that only -- it only  
2 exists here. The only analysis they did is in the context of  
3 deaths. I don't have another RAP that says, well, we're  
4 having migrations and we don't find a design problem and we  
13:02:43 5 ignore this and -- there are none. The only thing that exists  
6 that addresses anything like that is the exhibit I showed you,  
7 which doesn't have -- there is no analysis.

8 The only place the analysis takes place are in these  
9 documents. And so we can't present our case without  
13:02:56 10 presenting these documents in the context in which they  
11 happen. That's the problem.

12 THE COURT: This argument would be very persuasive to  
13 me if cephalad migration had continued in the G2 and the G2  
14 line of filters. But the problem that caused the cephalad  
13:03:24 15 migration deaths was fixed by the widening of the base,  
16 largely.

17 So it -- I mean, it seems to me it's -- what you're  
18 arguing is this careless, insensitive company that didn't do a  
19 root cause analysis and didn't do adequate testing may have  
13:03:45 20 solved the problem that was causing the deaths, but because  
21 they were careless they introduced a new problem that hit our  
22 client. That seems to me to be your our argument.

23 Am I misunderstanding?

24 MR. STOLLER: That is part of it, yes. I mean, it's  
13:04:00 25 part of the argument. The argument is a bit broader than

13:04:02 1 that.

2 The argument is that what they did and why they did  
3 it was a reaction to this. Would they have -- and, again, I'm  
4 going to go back to the diameters or the measurements here.

13:04:16 5 They went from 32 -- remember, these things are indicated for  
6 use in a 28-millimeter vena cava. Right? And I could draw  
7 concentric circles, but the Recovery is 32. So it's only  
8 marginally wider than the indicated vena cava. Right? They  
9 go from 32 to 40. They make a dramatic change in the diameter  
13:04:41 10 of that. And that dramatic change is because they're  
11 overreacting to this.

12 They never figure it out -- they are doing the -- of  
13 course they reacted to the fact that there were deaths. And  
14 they tried to -- we know, because we've presented subsequent  
13:04:57 15 evidence, and you've seen it, that there continue to be  
16 cephalad migrations. Not at the same rate, but, yeah, they  
17 did continue to have that happen.

18 I'll characterize it as overreaction. It's never an  
19 overreaction to do something in response to a death. But what  
13:05:12 20 they didn't do is what a reasonable, careful, and prudent  
21 company should have done, which is they should have taken it  
22 off the market in the first place, and then you have nothing  
23 else. Right?

24 So our first argument is they should have taken this  
13:05:25 25 off the market, because if you take this off the market and

13:05:27 1 you do what you should have done in the first instance, which  
2 is a reasonable clinical trial, you do the right studies, the  
3 right testing, the right FEA analysis, and all those sort of  
4 things, and figure out what this device is supposed to be and  
13:05:43 5 what it should be in order to perform safely in the body.  
6 Nothing that happens after that ever happens because this  
7 device simply isn't on the market.

8 But on top of that, instead of doing that, which  
9 would have been the reasonable and prudent thing to do, they  
13:05:55 10 reacted and went, well, we're going to do something in  
11 response to the deaths, but it's not going to be we're going  
12 to take it off the market, we're just going to widen this  
13 thing really big without any testing of it. And you only  
14 evaluate the reasonableness of those activities in the context  
13:06:08 15 of how it happened.

16 Again, there's no independent analysis anywhere that  
17 says, oh, well, we've got a migration issue generally, and the  
18 way to solve migrations is to widen the base, and we've done a  
19 reasoned analysis of, well, we're at 32, so we're going to go  
13:06:23 20 to 34 or 36. There's nothing like that.

21 The context of the -- what -- in my mind,  
22 mathematically, a 25 percent increase in the diameter of this  
23 base in a -- from -- to 40 milligrams in something that's  
24 supposed to be no larger than 28 is a significant overreaction  
13:06:40 25 as a result of exactly what happened here.

13:06:43 1           You can't untangle them and present like, well, if  
2           there hadn't been deaths, they would have done the same thing.  
3           And that's the problem. We don't know what they would have  
4           done.

13:06:51 5           The only context in which they did any analysis and  
6           took any action was in the context of these deaths. And  
7           without -- if you take them away, one, I don't know how you do  
8           it, because I don't have, then, I don't have where are they  
9           looking at this? What are they doing in terms of these  
13:07:06 10          investigation reports and their remedial action plans? It  
11          simply doesn't exist. The only place the analysis happened  
12          and the reaction is out of those.

13          And what the jury should get to hear in assessing the  
14          reasonableness of their actions is they did not -- they came  
13:07:20 15          up with excuses. They didn't do -- they did not do what they  
16          should have done, which is they should have taken it off the  
17          market and they should have figured out why it was happening  
18          the way it was so that when they moved to a larger or wider  
19          base, they did so in a reasonable way rather than something  
13:07:39 20          that was reactive. We're reacting to one problem and causing  
21          another.

22          THE COURT: It sounds to me as though you're arguing,  
23          Mr. Stoller, that there should be no limit on the death  
24          evidence that you can present.

13:07:57 25          MR. NORTH: No, I don't think that's true. I don't

13:07:59 1 think that's true.

2 THE COURT: What is the reasonable limit?

3 MR. NORTH: I think the reasonable limit is those  
4 places that are necessary in order to prove these parts of the  
13:08:02 5 case. There's other death --

6 THE COURT: What are they? That was the point of  
7 today's hearing: What's the stuff that's really necessary?

8 MR. STOLLER: I've given you the -- that's what I'm  
9 saying. I've given you the stuff that's necessary. I've  
13:08:14 10 given you the testimony of Mr. DeCant. I've given you --

11 THE COURT: Okay. So are you saying that if I allow  
12 these three depositions and these exhibits, that is  
13 sufficient?

14 MR. STOLLER: I think there are two or three other  
13:08:25 15 exhibits, and that would be it. But they're the same --  
16 they're the other reports along the way. I don't believe  
17 there's other evidence out there that becomes necessary.

18 And, as I said, they came back to us and said, look,  
19 here's some redactions and we said we'll withdraw it, we don't  
13:08:41 20 think that is necessary.

21 I think there's other testimony out there that is not  
22 related to these that we wouldn't present because it's not  
23 necessary to present these issues that we've talked about.

24 But we didn't give you Ms. Wong's testimony with  
13:08:55 25 respect to her exhibit. So that would be necessary in

13:09:00 1 addition to Mr. Ganser's. But it is literally about these  
2 exhibits and a couple of more that come up, and you'll see  
3 them in the transcript. We didn't give you all. There's  
4 another three or four in the DeCant deposition, which is the  
13:09:13 5 places where they're doing analysis, and we've cut that. If  
6 you read that testimony, you'll see what it reads like. It  
7 refers to the documents and the contents of them.

8 THE COURT: All right.

9 MR. STOLLER: I'll have a seat.

13:09:25 10 THE COURT: All right.

11 Well, plaintiff has argued for 55 minutes. I've got  
12 to be downstairs in 15 minutes.

13 MR. NORTH: I think I can go in five, Your Honor.

14 THE COURT: Okay.

13:09:44 15 MR. NORTH: Your Honor, as I understood the process  
16 today or the procedure contemplated, it was simply to  
17 determine, the Court having decided under Rule 403 that  
18 cephalad migration deaths should be excluded, whether this  
19 prevented the plaintiff, as they argued, from presenting  
13:10:01 20 testimony and evidence regarding cephalad migration  
21 investigation or root cause analysis, whether they could do  
22 that independent of the deaths.

23 In an effort to show and demonstrate that they could,  
24 we took some of the -- four of the six exhibits they presented  
13:10:16 25 and had them redacted in a way that we believe is consistent

13:10:20 1 with demonstrating that they can do exactly what they want to  
2 do without the reference to death.

3 If I could approach?

4 THE COURT: You may.

13:10:40 5 MR. NORTH: These were shared via e-mail with  
6 Mr. Stoller yesterday.

7 THE COURT: Have you given them a copy?

8 MR. STOLLER: I have a copy, Your Honor.

9 THE COURT: Okay.

13:10:47 10 MR. NORTH: The first, Your Honor, is the health  
11 hazard evaluation that Mr. Stoller discussed at length. If  
12 you look at the redactions proposed, they are very minimal,  
13 and it completely preserves the entire gist of the analysis  
14 and takes out the references to death.

13:11:17 15 The second document is the remedial action plan. It  
16 talks -- it removes a few small isolated references to death,  
17 and the entire gist of the analysis is still available for the  
18 jury.

19 The third document takes out the references to death,  
13:11:42 20 but still provides the fact that monthly reports were going --  
21 about complications, including cephalad migrations, were going  
22 to the management.

23 The next one is a filter migration meeting minutes.  
24 This was actually minutes convened -- of a group convened  
13:12:08 25 after a report of a migration death, but its charge was to

13:12:13 1 look broader than just a death, but to look at cephalad  
2 migration. And it shows that you can present all the  
3 testimony -- I mean all the evidence they want of the analysis  
4 done.

13:12:26 5 There are probably a dozen other remedial action  
6 plans and health hazard evaluations on these same issues,  
7 Recovery filter fracture and migration, that could likewise be  
8 redacted in the same fashion and would allow the plaintiff to  
9 present the evidence of Recovery filter testing, design, and  
13:12:47 10 complications that they desire to, but simply not mention the  
11 word "death."

12 And we submit that what we've heard for the last 55  
13 minutes are basically their justification for just including  
14 the word "death." The fact of the matter is they can get the  
13:13:03 15 same principles in front of the jury without that.

16 And Ms. Helm is just going to make a brief comment  
17 about the deposition transcripts which she looked at for us.

18 THE COURT: Okay.

19 MS. HELM: Your Honor, I actually think that the  
13:13:19 20 deposition transcripts are easier to redact than the documents  
21 themselves. And what we did and what plaintiffs have  
22 submitted to you are the redactions that we proposed.

23 And if, for example, you look at Mr. Ganser on  
24 page 41, which is the very first page of testimony, the only  
13:13:45 25 redaction we made was to the word "death." So the sentence

13:13:50 1 now reads "the Recovery needed to be redesigned because of  
2 issues that related to migration fractures and open heart  
3 surgeries."

4 So all of the points they want to make with these  
13:14:01 5 witnesses about what was or wasn't done and about how they  
6 reacted or didn't react, it all still exists. We did not  
7 attempt to pull out huge sections of the transcripts.

8 And we're prepared to go through every transcript  
9 that discusses death and make our proposed redactions and  
13:14:22 10 submit them to the plaintiff to either agree or disagree, and  
11 then let the Court -- but we didn't -- I mean, if you read  
12 through these, and we actually went so far as to have the  
13 videos cut, and it reads just fine. That sentence reads that  
14 you didn't do anything because you had migrations, fractures,  
13:14:37 15 and open heart surgeries, and it just takes out the word  
16 "death," but all the substance of the testimony about what the  
17 company was or wasn't doing -- and I could go through  
18 Mr. DeCant about what root cause analysis the company did or  
19 did not find, all of the substance is still very much there.

13:14:55 20 So I believe that the depositions can be redacted,  
21 and we can get redacted to versions to them by Sunday to  
22 address and review.

23 In the interest of time, I'm not going to go through  
24 more examples, but I think they're actually simpler than the  
13:15:12 25 exhibits.

13:15:13 1 THE COURT: Okay.

2 Mr. Stoller, did you have any final comments? Or  
3 Mr. Lopez?

4 MR. STOLLER: Let me -- let me address the last point  
13:15:24 5 and give you an example. The problem with the redactions they  
6 propose is they change testimony. They change the answers the  
7 witness gives to something other than what they are.

8 And the example I'm going to start with is  
9 Mr. Ganser, page 254, and here's the question without the  
13:15:44 10 redaction, and then the question with the redaction.

11 "Sir, you're already redesigning this product because  
12 of its migration because of it's -- because it's causing death  
13 as of April 2004, aren't you?"

14 "Answer: We're redesigning the product."

13:15:56 15 That is not the same question and answer as, "Sir,  
16 you're already redesigning this product because of its  
17 migration as of April of 2004."

18 That is not -- that wouldn't necessarily be the same  
19 answer.

13:16:09 20 THE COURT: Well, but you're quoting the question.  
21 That's --

22 MR. STOLLER: I understand that, but that's the  
23 problem with it.

24 THE COURT: Well, no. Hold on a minute. The answer,  
13:16:16 25 the evidence in that exchange is we're redesigning the

13:16:20 1 product. So what he's testifying to is that in April of 2004,  
2 they're redesigning the product.

3 MR. STOLLER: Let's go back two pages.

4 THE COURT: He didn't adopt --

13:16:30 5 MR. STOLLER: Okay. Fair enough. Let me give you --  
6 I looked at the question there. The yes/no answer is changed  
7 by that. I'll give you a yes/no answer. 237, starting line  
8 21.

9 "Don't you think any consumer, regardless of product,  
13:16:42 10 before they buy a product that could potentially cause serious  
11 injury and death would want to know whether or not the company  
12 that was selling the product had determined that the risk of  
13 serious injury and death was either unacceptable or  
14 undesirable?"

13:16:56 15 "Answer: I would assume that most consumers would."

16 Is that answer the same when you take out the word  
17 "or death"? We don't know. This alters the -- when -- you  
18 can't simply remove it. I just don't think it is right. I  
19 think you can look through these, and, again, we looked  
13:17:12 20 through some of them and we said we'll withdraw them.

21 But the problem is that it's not easily extractible.  
22 I think a lot of these change. You change the question, the  
23 answer may not be the same. You change the answer, the  
24 answer's not the same.

13:17:28 25 I'm going to go back to the HHE, which Mr. North

13:17:31 1 said, well, look, you can readily extract that stuff. Except  
2 that he's not analyzing points along -- on different issues at  
3 the same time. I mean, how do you extract from their  
4 knowledge and say, well, let's just pretend this thing didn't  
13:17:46 5 happen, it wasn't part of what was at play at the time when  
6 they're doing these analyses?

7 The problem is that the deaths from migration is --  
8 it's why they did everything from there on out. It's  
9 interwoven in the fabric.

13:18:06 10 If we try to extract it through these little  
11 excisings, it takes out something that actually happened, that  
12 was the basis for their actions, and pretends it didn't exist.  
13 And their actions may not have been the same. When you take  
14 the word about "migrations and deaths" and take "deaths" out,  
13:18:24 15 they may not have done anything with respect to migrations.  
16 In fact, the evidence suggests they wouldn't have, because  
17 they never did any independent analysis and said, we've got  
18 migrations going towards the heart. And without regard to  
19 deaths, oh, well, we don't -- you know, we're going to do  
13:18:42 20 something, we're not going to do something. We have no idea.  
21 We would literally be fabricating evidence to give to this  
22 jury by taking out those deaths and saying, well, they would  
23 have done this, and this is what they did without that there.  
24 They did this because of the deaths.

13:18:55 25 I don't know how you --

13:18:58 1 THE COURT: I understand your argument.

2 MR. STOLLER: Again, it's interwoven with what --

3 THE COURT: All right. We are out of time. I've got

4 to --

13:19:03 5 MR. LOPEZ: If I can take 60 seconds, Your Honor,

6 just to make two quick points.

7 THE COURT: 60 seconds.

8 MR. LOPEZ: You recall the product hold? That

9 document says if there is one more hospitalization we're going

13:19:14 10 to reinstate the hold. There was a death instead of a

11 hospitalization, and they never put the hold back on.

12 We submit that the death is more serious than a

13 hospitalization.

14 They're going to say that the FDA did not tell them

13:19:28 15 to recall the Recovery filter. And we're not going to be able

16 to put on evidence that they did not share with the FDA the

17 statistically significant evidence of statistics of

18 Natalie Wong and Dr. Lehmann. Completely unfair.

19 If -- we're going to submit, and I think maybe their

13:19:43 20 own experts would agree, that had the FDA been provided with

21 that information, the FDA might have said, you know, this

22 might be the rare occasion where we're going to mandate a

23 recall.

24 THE COURT: Okay. I understand what's been argued,

13:19:55 25 and I will take this under advisement and get you a ruling on

13:20:01 1 the issues we've talked about today. And otherwise we'll plan  
2 to see you at 8:30 a.m. on May 15th.

3 MR. NORTH: Thank you, Your Honor.

4 MS. HELM: Your Honor, what do we do about the  
13:20:14 5 depositions that are due to you on Monday?

6 THE COURT: Well, I don't know. Because I -- when I  
7 said that, I had thought that I might be able to get you an  
8 answer at this hearing. I can't do that. I need to read  
9 these documents. And I don't know if I can get it done by the  
13:20:33 10 end of the day.

11 If I haven't done it, it doesn't make any sense for  
12 you to do the deposition. So let's say that if I don't get  
13 you a ruling by the end of today, the depositions aren't due  
14 on Monday.

13:20:46 15 If I don't, I'll get you a ruling on Monday, and then  
16 we'll say the depositions are due on Wednesday, or something  
17 like that.

18 Okay. Thank you all.

19 (End of transcript.)

13:20:56 20 \* \* \* \* \*

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 8th day of May, 2018.

s/ Patricia Lyons, RMR, CRR  
Official Court Reporter